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Psychosocial risk factors in the development of fibromyalgia; and Compassion-Focused Therapy for chronic pain: mediators of improvement

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***

This thesis is dedicated to my parents, who continually devote their lives to secure a future for their family. Thank you for all that you do.

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Thesis Abstract

Background: Chronic pain is a worldwide problem that can cause a great level of disability in a person's life. The aetiology of conditions such as fibromyalgia is still under debate, and there are many biological, psychological and social hypotheses for its development. Past research in this area has explored the predictive impact of abuse and post-traumatic stress, but these are just some of the factors implicated in a wider picture. Psychological approaches to chronic pain have focused on Cognitive Behavioural Therapy and Acceptance and Commitment Therapy, two approaches that result in similar outcomes. Currently, very little research exists on Compassion-Focused Therapy (CFT) for chronic pain, even though the literature suggests conceptual overlaps between CFT and existing therapies.

Objective: This thesis aims to reconcile existing information on the psychosocial risk factors that lead to the development of fibromyalgia (Chapter 1) and evaluate the suitability of an 11-week Compassion-Focused Therapy group intervention for adults with chronic pain (Chapter 2). Furthermore, this research also seeks to explore self-compassion, psychological flexibility and psychological inflexibility as potential mediators of improvement in outcome. Limited research and clinical resources can be better used by focusing on *how* therapies work, instead of *if* they work against similar treatments that have already proven efficacious.

Methods: The evidence base for psychosocial risk factors in the development of fibromyalgia is systematically reviewed in Chapter 1. Electronic databases were searched for various descriptions of fibromyalgia, risk factors and observational study designs. Populations that included physical co-morbidities were excluded. In Chapter 2, 122 participants attended the Pain Management Programme at the NHS Lothian Chronic Pain Service. Outcome measures were collected at three timepoints (pre, mid and post-group). One-way ANOVAs were used to evaluate the efficacy of the intervention, along with multiple regressions to perform mediation analysis.

Results: 10 studies from a search of 889 potentially relevant studies met the inclusion criteria for systematic review. Most of these studies were deemed to be of good quality. Commonalities across studies included appropriate selection of control and comparison groups, valid random sampling techniques and adequate length to follow-up in the case of cohort studies. Studies, however, varied across their methods in ascertaining fibromyalgia and researchers relied on their own reports to establish outcomes. In Chapter 2, statistically significant improvements were demonstrated in measures of pain interference, anxiety, depression, psychological flexibility, psychological inflexibility, self-compassion and mental wellbeing by the end of the PMP. The largest improvements were found to occur in the second half of the PMP. Self-compassion was shown to mediate improvements in pain interference, whereas psychological flexibility and psychological inflexibility was shown to mediate improvements in depression and mental wellbeing. Neither predictor variable mediated improvements in anxiety.

Discussion: Prospective cohort studies represent the best evidence for determining risk factors. Depression, anxiety, childhood adversity, work stress and low education were found to be risk factors for developing fibromyalgia. Based on these results, it is recommended that more conservative estimates of effect size be used. This research also provides evidence for the use of CFT as a group intervention for chronic pain. It can be concluded that pain interventions targeting psychological flexibility and psychological inflexibility are likely to be further improved by emphasising self-compassion. CFT and ACT already share similar values, despite their differing theoretical backgrounds. Patients will be able to benefit from a combined approach since self-compassion, psychological flexibility and psychological inflexibility were shown to mediate improvement in different outcomes.

Lay Summary

Chronic pain is pain that lasts longer than 3 months. Unlike acute pain, it is not an indicator of damage to the body. Fibromyalgia is a long-term condition that causes chronic pain all over the body, as well as other symptoms such as fatigue and problems with memory and concentration. The causes of fibromyalgia are still under debate, and Chapter 1 of this thesis compiles information about the psychological and social factors related to the development of fibromyalgia. The results in Chapter 1 found that depression, anxiety, childhood adversity, work stress and low education were risk factors for developing fibromyalgia.

Pain Management Programmes are a recommended group treatment for people with chronic pain, involving input from different professionals using exercise, education and psychological therapies. These multidisciplinary teams help people manage the negative experiences associated with living with chronic pain (such as distressing thoughts and feelings); the aim is not to get rid of the pain. Often people with chronic pain can feel shameful about their condition. Compassion-Focused Therapy (CFT) is a type of psychological treatment that helps people to view themselves and their difficulties in a kinder, less critical way (self-compassion). Currently, no research is available on the effectiveness of CFT in managing chronic pain. Research, however, does exist to show that there are elements of other treatments that overlap with elements of CFT. One example of this overlap is psychological flexibility. Psychological flexibility is the ability to recognise and adapt to life circumstances, by pursuing long-term life values (e.g. being a supportive parent) instead of short-lived ones (e.g. avoiding pain).

Chapter 2 aims to establish how CFT might work for people with chronic pain. This study aims to investigate self-compassion, psychological flexibility and psychological inflexibility as possible tools in the effectiveness of CFT on people with chronic pain. It was found that CFT is effective as a group intervention for chronic pain, and the largest improvements occurred in the second half of the group. Self-compassion explained improvements in pain interference; psychological flexibility and psychological inflexibility explained improvements in depression and mental wellbeing.

Chapter 1: Systematic Review

A systematic review of the psychosocial risk factors in the development of fibromyalgia

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Abstract

Objective: Previous research in this area has focused on the predictive impact of abuse and post-traumatic stress on the risk of developing fibromyalgia. The aim of this systematic review is to synthesise information on the wider psychosocial risk factors for fibromyalgia syndrome (FM or FMS).

Methods: Embase, EMCare, MEDLINE and PsycINFO were systematically searched for appropriate papers. Only published, peer-reviewed, English articles that focused on adult populations were included. Search terms covered various descriptions of fibromyalgia, risk factors and observational study designs. Populations that included physical co-morbidities were excluded. A second reviewer independently assessed the quality of 3 papers (30%).

Results: 10 studies from a search of 889 potentially relevant studies met inclusion criteria. Most of these studies were deemed to be of good quality. Meta-analysis was not possible due to the heterogeneity of study designs and outcome measures. Commonalities across studies included appropriate selection of control and comparison groups, valid random sampling techniques and adequate length to follow-up in the case of cohort studies. Studies, however, varied across their methods in ascertaining fibromyalgia and researchers relied on their own reports to establish outcomes.

Discussion: Prospective cohort studies represent the best evidence for determining risk factors. Depression, anxiety, childhood adversity, work stress and low education were found to be risk factors for developing fibromyalgia. It is recommended that more conservative estimates of effect size be used in this area. Further associations were found between a number of variables, but due to limitations in study design, only inferences about these correlations can be made.

Keywords

Psychosocial risk factors; fibromyalgia; predictors *Word count: 6,104*

1. Introduction

Fibromyalgia (FM) or fibromyalgia syndrome (FMS) is characterised by a history of widespread pain of at least three months' duration, and pain in 11 out of 18 specified tender points in the body. It is often associated with stiffness, sleep disturbances and fatigue, although diagnosis does not require all of these symptoms to be present at the same time[1]. Cognitive difficulties, especially in memory and learning ("fibro-fog"), and mood disturbances are also linked to the condition[2,3]. Central to fibromyalgia is an overly reactive and permanently altered nociceptive system[4]. Through a process of central sensitisation, pain sensitivity is heightened (hyperalgesia) and pain is experienced in response to typically innocuous stimuli (allodynia)[5].

Fibromyalgia is estimated to affect 2.6% of the population worldwide, and has been reported to be more prevalent in women, those over the age of 50, those with lower attainments in education and low socioeconomic status (see Queiroz[6] for a synthesis of 26 prevalence studies worldwide). There is some disagreement about the relationship of these sociodemographic variables to the development of fibromyalgia[7]; study designs in this area of research are often not equipped to determine the timeline of risk factors. A prospective study by Davies et al.[8] reported that the relationship between new chronic widespread pain and socioeconomic status can be attributed to psychological factors, which illustrates a complex picture of interrelated variables exacerbating long-term pain.

Due to the heterogenous nature of fibromyalgia, its aetiology is debated and multi-layered. Genetic, neurohormonal and biological explanations have been proposed (e.g. serotoninergic, dopaminergic and catecholaminergic systems[9]; deep tissue impulse input[10]), however, the contributing psychological mechanisms are less clear. Anxiety and depression are associated with fibromyalgia[11] and high levels of psychological distress and illness behaviour (medical-care seeking and fatigue)[12] have been found to increase likelihood of persistent pain. Stress has been noted as a precipitating factor, but evidence for this is conflicting[13]. A narrative review by Gupta and Silman[14] compiled information on how chronic stress exacerbates and maintains changes in hormonal systems and

neurotransmitters, which contributes to the development of the symptoms of fibromyalgia, such as pain and fatigue. Pre-morbid psychological disposition also contributes to sustaining these relationships, for example, inappropriate overactivity and perfectionistic traits perpetuate high levels of stress[15].

There are currently no systematic reviews that focus only on the psychosocial risk factors implicated in the development of fibromyalgia. An older Spanish review[16] included studies up to 2007 and identified risk factors such as stress and occupation, and other physical risk factors such as Hepatitis C and smoking. Seven of the included papers in Restrepo-Medrano's[16] review were theoretical reviews and new empirical research has emerged since then. The aim of this current review is to collate existing and new research on the psychosocial risk factors, which can be defined as internal and individual (e.g. depression) or external and structural variables (e.g. work environment)[17].

Previous systematic reviews in this area have focused solely on the association between trauma and fibromyalgia[18,19]. Hauser et al.'s[18] meta-analysis noted significant associations between physical and sexual abuse and fibromyalgia, but not emotional abuse. Low study quality was a confounding factor. The authors suggest that the indistinct nature of emotional abuse may be problematic to conceptualise and its definition varied across studies. Since depression is related to reported childhood emotional abuse[20], it is significant that none of the included studies in Hauser's systematic review looked at the effect of depression in reporting the incidence of abuse.

A systematic review by Yarden et al.[19] found significant associations between fibromyalgia and past physical or psychological trauma. They propose a model of genetic susceptibility, aggravated by physical, medical or psychological triggers, which leads to central sensitisation. In their model, the development of fibromyalgia and PTSD is mediated by factors such as gender and co-morbid psychopathology. Many of the studies included in Hauser's[18] and Yarden's systematic reviews rely on retrospective data and are therefore limited in what conclusions can be drawn regarding the causality of these variables in the development of fibromyalgia.

There is ongoing criticism around whether or not fibromyalgia should be considered a distinct classification from chronic widespread pain[11], with some debating the psychogenic nature of the condition[6]. Fibromyalgia has been shown to be associated with more severe symptoms, greater limitations in function and fewer periods of remission[21,22]. It appears to represent an extreme end of the spectrum of chronic widespread pain, and as such, is treated as a separate entity in this review.

1.1 Rationale

To date, no systematic reviews have been published that focus solely on the psychosocial risk factors for developing fibromyalgia. Previous reviews in this area are either outdated[16] or focus only on the relationship between trauma and fibromyalgia[18,19]. The aim of this systematic review is to synthesise empirical evidence on the psychosocial risk factors for developing fibromyalgia, which will include psychological, occupational and social factors. Observational study designs are reviewed as standard practice in risk factor research, since life and health events cannot be randomly assigned[23].

1.2 Review Question

Based on existing observational research, what are the psychosocial risk factors that are implicated in the development of fibromyalgia?

2. Method

A systematic search of peer-reviewed literature was conducted; this protocol was registered on PROSPERO (https://www.crd.york.ac.uk/prospero/display_record.php?RecordID=119740) on the 25th January 2019.

Guidance was taken from the Centre for Reviews and Dissemination (https://www.york.ac.uk/media/crd/Systematic_Reviews.pdf) and the Cochrane Collaboration (https://training.cochrane.org/handbook).

2.1. Search Strategy

Embase, EMCare, MEDLINE and PsycINFO were searched for appropriate papers in November 2018. No date limits were set and only papers published in English were included due to the impracticality of translation services. The following search terms were used: i) ("fibromyalgia" OR "fibromyalgia syndrome" OR "FM" OR "FMS" OR "widespread pain") AND ii) ("risk factors" OR "predictors" OR "psychosocial factors" OR "psychological factors" AND iii) ("cross-sectional" OR "case-control" OR "cohort"). 889 papers were identified from this search. The PRISMA flowchart[24] (Figure 1) details the process of appropriate paper identification.

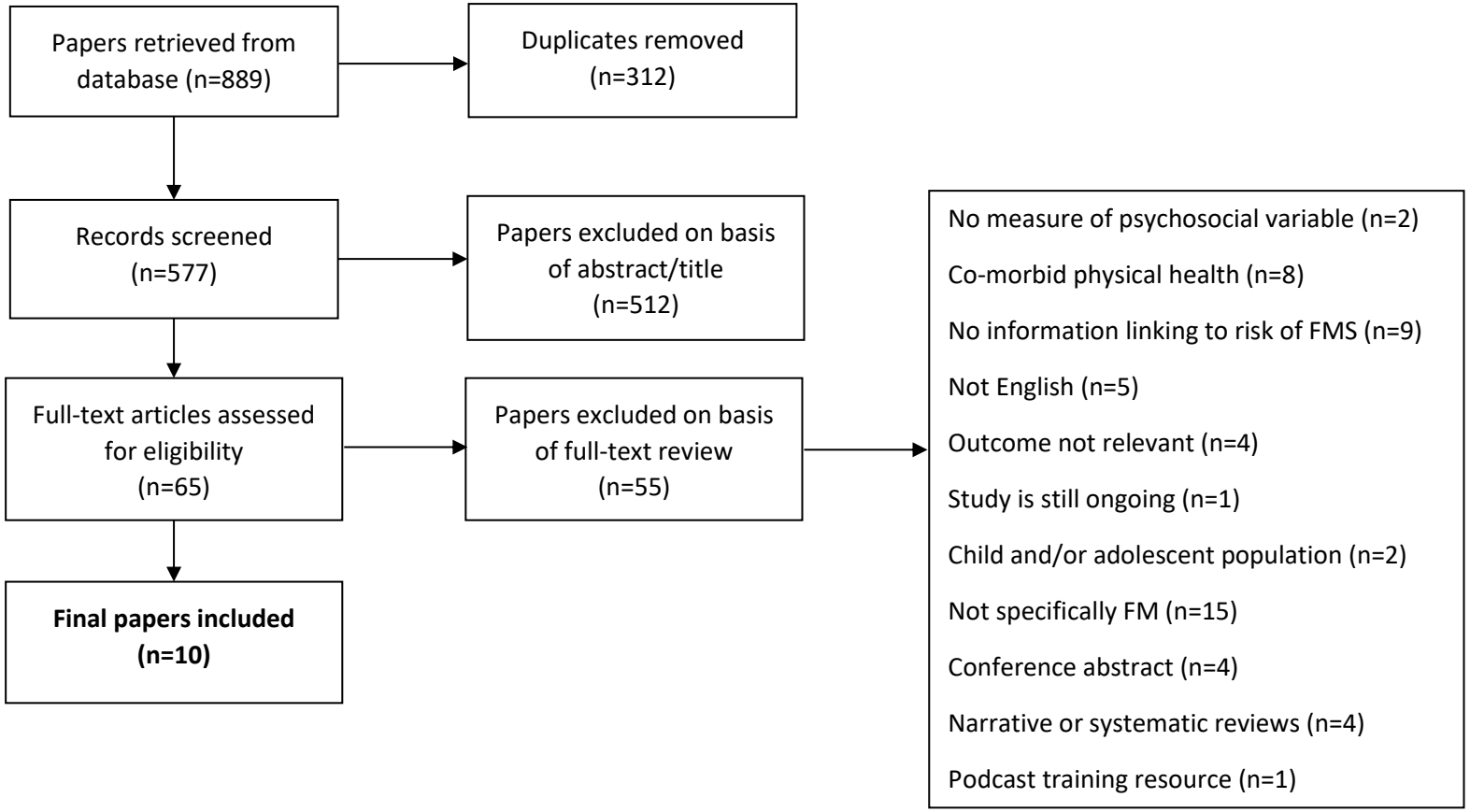
2.2. Inclusion and Exclusion Criteria

Peer-reviewed studies were included based on the following criteria: 1) adult population (18+ years), 2) specific focus on fibromyalgia (not widespread pain or other general chronic pain), 3) measurement of at least one psychosocial factor and 4) identification or analysis of risk of developing fibromyalgia. Studies were excluded if the target population was 1) children or adolescents, or 2) physical co-morbidities (e.g. arthritis) and if the paper was a review article.

2.3. Data Extraction

Data was extracted using a form (Appendix 2) based on the STROBE Statement[25], which covered information on a study's methods (study design, size, participants, variables, data measurement and statistical methods), results (response rate, descriptive data and statistical analyses) and discussion (key results, limitations, strengths, interpretation and generalisability). Only psychosocial outcomes were recorded.

Figure 1 Literature search flowchart



2.4. Quality Assessment

The methodological quality of the included studies was assessed using criteria (Appendix 3) based on the Newcastle-Ottawa Quality Assessment Scale[26] and Murray et al.'s[23] recommendations for social scientists undertaking risk factor research. Quality was assessed over several areas: the study's definition of fibromyalgia, sampling, data type, sample size, selection and definition of the non-fibromyalgia group (where applicable), comparability, ascertainment of fibromyalgia, outcome, response rate and statistical testing. A quality criteria checklist was created based on these areas to consider the three different study designs in the final sample: cross-sectional, case-control and cohort. Each study was given an overall rating of risk of bias. A second reviewer independently rated the quality of 3 randomly selected papers. Disagreements were discussed and reconciled.

3. Results

3.1. Search Results

889 potentially relevant studies were retrieved. 312 duplicates were removed and a further 512 studies were excluded on the basis of title and abstract screening. 65 full-text studies were assessed for eligibility and 55 studies were excluded (reasons for these exclusions are detailed in Figure 1), leaving a final sample of 10 studies included in the review.

3.2. Study Characteristics

The main characteristics of the 10 studies are detailed in Table 1. Of these studies, 8 used original data (i.e. the study was deliberately designed to recruit participants for a pre-defined purpose, not using secondary data analysis). Two of the total studies were cross-sectional in design[27,28], two were case-control[29,30] and six were cohort[31–36]. Most were based in Europe; three in the USA[28,31,35] and one in Lebanon[29]. The populations being investigated were predominantly female (52.7-100%). Samples were mainly recruited from population registries and hospitals; one sample was based on church

membership[31] and one was based on a group of veterans[28]. Mean age across the sample ranged from 27.7 to 49.2, where this information was available. Follow-up in cohort studies ranged from 2 to 25 years.

3.3. Quality Appraisal

Table 2 illustrates the overall quality ratings of the 10 included studies, ordered by risk of bias expressed as a percentage of total available '+' ratings; scores ranged from 56% to 92%. The lower rated studies indicated a higher risk of bias. Overall acceptability categories (such as 'good' and 'poor') were not assigned to individual studies due heterogeneity of study design. Most studies recruited adequate sample sizes[28–36], controlled for relevant confounding variables[27–34,36] and all employed appropriate statistical testing. Studies were generally found to be good quality, based on the ratio of positive to negative ratings. Studies that used a prospective study design[31–34,36] were rated higher quality, due to the fact that risk factors could be measured before fibromyalgia was diagnosed, instead of relying on people's retrospective recall. This is the ideal study design to deduce the time-ordering of variables in risk factor research. The prospective studies have been highlighted in Table 2, to indicate the difference in the quality of the evidence provided.

Common weaknesses included: reliance on self-report measures[28,31–34,36], inadequate method of ascertaining fibromyalgia[31,33,34,36] and inadequate response rate (or absence of reporting the response rate)[28–31,35]. Suitability of response rate was guided by Richardson[37] who suggested a 50% return rate on postal surveys is adequate in social science research. Five studies used the American College of Rheumatology (ACR)-1990 criteria to ascertain fibromyalgia[27,29,30,32,34], two of which further employed medical examination to confirm the diagnosis[27,29]. All studies that employed a follow-up were found to be of suitable length[31–34,36]; according to existing research, 2 years is the average time until a diagnosis of fibromyalgia is made[38]. Other studies that cited a longer average time to diagnosis were based on an older mean age[39].

Table 1 Included studies and their main characteristics

First author (Year), Country	**Study design / analysis**	**No. of FMS participants / controls (if applicable)**	**Assessment of FMS**	**Control group (if applicable)**	**Mean ± SD age in years FMS / controls (if applicable)**	**% female FMS / controls (if applicable)**	**Method of assessment and any validated measures used***	**Psychosocial factors and strength of relationship [η^2, *p*-value] or [OR (95% CI)]** (Note: η^2 calculated by author)
Bergman, S. (2005)[27], Sweden	Cross-sectional / regression	15 FMS out of 1,015 participants with chronic pain	ACR-1990, physician examination	Participants from the same population without pain and a further 3 pain groups	No mean reported. Age range 20-74	100	Questionnaire; SF-36, SEI	Low socioeconomic status** Immigrant [3.6 (0.8–16.6)] Poor housing [18.1(1.9–168.6)] Low education** No social support [2.4 (0.6–9.6)] Family history of chronic pain [6.2 (1.8–21.0)]
Choi, C.J. (2010)[31], USA	Cohort (1976-2002) / regression	136 FMS from 3156 participants	Self-report	Participants from the same population without FMS	No mean reported, minimum age 25	100	Questionnaire	Education [*ns*] Employment [*ns*] Marital status [*ns*]
D'Aoust, R. (2017)***[28], USA	Cross-sectional / ANOVA	76	LFESSQ-4 and LFESSQ-6 (two extra questions on fatigue)	Comparison group LFESSQ-4 vs LFESSQ-6	46.04 ± 10.71	100	Questionnaire; PCL-M, CES-D, PSS, SF-12, LFESSQ, PSQI	Income [*ns*] Depression [η^2=0.2186, *p*<0.0001] Stress [*ns*] Post-traumatic stress [η^2=0.1842, *p*=0.0001] Physical quality of life [*ns*] Mental quality of life [η^2=0.1535, *p*<0.005] Military sexual trauma [*ns*]
Forseth, K. (1999)[32], Norway	Cohort (1990-1995) / regression	43 FMS from 175 participants	ACR-1990	Participants from the same population without FMS	36.0 ± 7.0	100	Questionnaire	Anxiety [1.4 (0.3–5.8)] Self-assessed depression [3.3 (0.5– 2.0)] Vocational education [0.6 (0.1–3.1)] No formal education [2.6 (0.6–11.7)]

First author (Year), Country	Study design / analysis	No. of FMS participants / controls (if applicable)	Assessment of FMS	Control group (if applicable)	Mean ± SD age in years FMS / controls (if applicable)	% female FMS / controls (if applicable)	Method of assessment and any validated measures used*	Psychosocial factors and strength of relationship [η^2, *p*-value] or [OR (95% CI)] (Note: η^2 calculated by author)
Kivimaki, M. (2004)[33], Finland	Cohort (1998-2000) / logistic regression	47 FMS from 4,791 participants	Self-report; checklist of common chronic diseases	Participants from the same population without FMS	43.3	88.7	Questionnaire; HS	Work stress: High workload [1.03 (0.89–1.19)] Low decision latitude [1.00 (0.82–1.24)] Workplace bullying [1.37 (0.81–2.31)]
Markkula, R. (2016)[34], Finland	Cohort (1975-1990) / logistic regression	700 FMS from 8343 participants	ACR-1990	Participants from the same population without FMS	27.7 ± 7.3	52.7	Questionnaire	Education [0.89 (0.85–0.92)]
Masters, E. (2015)[35], USA	Retrospec cohort (2012-2011) / logistic regression	4,296 / 583,665	ICD-9 code	Participants from the same population without ICD-9 code for fibromyalgia	53.3 / 52.7	78.7 / 64.5	Retrospective database analysis	Depression [2.9 (2.7–3.1)] Anxiety/GAD [2.6 (2.4–2.8)] Bipolar [2.8 (2.2–3.6)] Panic [3.3 (2.7–4.2)] PTSD [4.4 (3.4–5.9)] Memory loss [2.4 (1.9–3.0)]
Moukaddem, A. (2015)*** [29], Lebanon	Case-control / logistic regression	34 / 136	ACR-1990, physician examination, medical tests	Participants from the same population with no history of MSK pain or rheumatic disease	No mean reported, minimum age 20	100	Questionnaire; VAS, GHQ-12	Ever married [*ns*] Residence location [2.24 (0.71–7.05)] Low education [*ns*] Low income [*ns*] Unemployed [*ns*] Employed [2.69 (1.04–6.93)] Psychological distress [1.45 (0.44–4.82)]

First author (Year), Country	Study design / analysis	No. of FMS participants / controls (if applicable)	Assessment of FMS	Control group (if applicable)	Mean ± SD age in years FMS / controls (if applicable)	% female FMS / controls (if applicable)	Method of assessment and any validated measures used*	Psychosocial factors and strength of relationship [η^2, *p*-value] or [OR (95% CI)] (Note: η^2 calculated by author)
Ruiz-Perez, I. (2009)[30], Spain	Case-control / logistic regression	287 / 287	ACR-1990, medical tests	Participants not diagnosed with FMS seen at the ENT department	47.8 ± 8.0 / 40.8 ± 12.4	100 / 100	Questionnaire; GHQ-12	Married [4.07 (2.46–6.75)] Separated [3.87 (1.93–7.73)] Unemployed [*ns*] Housewife [3.47 (0.98–12.22)] Employed [4.97 (1.45–17.02)] No education [7.01 (2.52–19.48)] Low income [*ns*] Having social support [0.47 (0.24–0.93)] Psychological distress [4.62 (2.68–7.97)] Frequent abuse [3.01 (0.84–10.97)]
Varinen, A. (2017)[36], Finland	Cohort (1998-2012) / chi-square, logistic regression	515 FMS from 11,924 participants	Self-report	Participants from the same population without FMS	No mean reported. Age range 20-54	85.0	Questionnaire; BDI	Marital status [*ns*] Education [*p*<0.001] Depression [*p*<0.001] *Childhood adversities:* Parental divorce [1.34 (1.05–1.72)] Financial difficulties [1.45 (1.18–1.77)] Serious conflict [1.40 (1.14–1.72)] Serious illness [1.27 (1.05–1.55)] Fear of family member [1.60 (1.28–2.01)] Alcohol problems [1.25 (1.02–1.53)]

*Abbreviated measures: BDI: Beck Depression Inventory; CES-D: Centre for Epidemiologic Studies Depression Scale; CTQ: Childhood Trauma Questionnaire; GHQ-12: General Health Questionnaire; HS: Harris Scale of workload; LFESSQ: London Fibromyalgia Epidemiology Study Screening Instrument Questionnaire; PCL-M: Post Traumatic Checklist – Military; PDI: Pain Disability Index; PHQ-4: Patient Health Questionnaire; PSS: Perceived Stress Scale; PSQI: Pittsburgh Sleep Quality Index; SEI: Swedish Socioeconomic Classification; SF-12: Shortened Medical Outcomes Short Form Health Survey; SF-36: Medical Outcomes Short Form Health Survey; VAS: Visual Analogue Scale. **Missing OR is due to all subjects (n=15) being in that category ***Secondary data analysis

Table 2 Quality assessment of studies

Quality Criteria	Sampling	Data type	Sample size	Selection of controls and comparisons	Definition of controls and comparisons	Comparability	Ascertainment of FMS	Ascertainment of absence of FMS at start	Assessment of outcome	Response rate	Length of follow-up	Statistical testing	Overall quality rating (%)
Authors (Year)	Cross-Sectional												
D'Aoust (2017)	-	NA	+	+	-	+	+	NA	-	-	NA	+	56
Bergman (2005)	+	NA	-	-	-	+	+	NA	-	+	NA	+	56
	Retrospective												
Ruiz-Pérez (2009)	-	-	+	+	+	+	+	NA	-	-	NA	+	60
Moukaddem (2015)	+	-	+	+	+	+	+	NA	-	-	NA	+	70
Masters (2015)	+	-	+	+	+	-	+	+	+	NA	-	+	73
	Prospective												
Choi (2010)	-	+	+	+	+	+	-	+	+	-	+	+	75
Varinen (2017)	+	+	+	+	-	+	-	-	+	+	+	+	75
Kivimaki (2004)	-	+	+	+	+	+	-	+	-	+	+	+	75
Markkula (2016)	+	+	+	+	-	+	-	+	-	+	+	+	75
Forseth (1999)	+	+	+	+	+	+	+	+	-	+	+	+	92

3.4. Study Outcomes

Study outcomes were heterogenous in nature and 17 psychosocial risk factors were identified. These risk factors were grouped into the following categories: psychological, occupational and social. Small (1.68), medium (3.47) and large (6.71) effect sizes for odds ratios are based on recommendations by Chen et al.[40] and small (.02), medium (.13) and large (.26) effect sizes for eta squared calculations are based on recommendations by Bakeman[41]. Where possible, results from prospective studies have been detailed first to indicate the higher quality of the evidence, followed by retrospective studies,

which are intrinsically prone to more bias. Findings from cross-sectional studies are reported last and termed as 'associations', instead of predictive factors, in the absence of time-ordering in their design.

3.4.1. Psychological Factors

Forseth et al.'s prospective study[32] found a small effect of anxiety [1.4 (0.3–5.8)] on the risk of developing fibromyalgia. This is supported by a retrospective longitudinal finding by Masters et al.[35], who reported a higher likelihood of receiving a diagnosis of fibromyalgia one year following a diagnosis of anxiety, with a small-medium effect [2.6 (2.4–2.8)].

Forseth et al.[32] reported a medium effect of self-assessed depression [3.3 (0.5–2.0)]. This is supported by another prospective study, Varinen et al.[36], whose results showed a significant relationship between depression and fibromyalgia [$p < 0.001$], however, there was not enough information in the paper to calculate an effect size. This result was based on the Beck Depression Inventory (BDI[42]), contrasting with Forseth et al.'s[32] single question regarding self-reported depression. A predictive link between depression and fibromyalgia [2.9 (2.7–3.1)] was highlighted in Masters et al.'s[35] paper, however, causality cannot be confidently inferred due to its retrospective design. A large effect of depression was found by D'Aoust et al.[28] [$\eta^2 = 0.2186$, $p < 0.0001$], which also suffers from the same limitation as a cross-sectional study.

Two retrospective studies explored psychological distress using the General Health Questionnaire (12-item) (GHQ-12[43]): Ruiz-Perez et al.[30] reported a medium effect [4.62 (2.68–7.97)] and Moukaddem et al.[29] a small effect [1.45 (0.44–4.82)]. These two studies rated similarly on quality criteria, with the exception of the latter employing a better sampling strategy, more representative of fibromyalgia in the community, which suggests that a more conservative estimate may be more reliable. D'Aoust et al.'s[28] cross-sectional study explored quality of life using the mental component of the Shortened Medical Outcomes Short Form Health Survey (SF-12[44]) and reported a large effect size [$\eta^2 = 0.1535$, $p < 0.005$], highlighting a strong association between health related quality of life and fibromyalgia. This finding is comparable to the previous results on psychological distress, as the mental component

of the SF-12 has been found to be better at screening anxiety and depression than the GHQ-12[44]. D'Aoust et al.[28] did not find a significant association between stress and fibromyalgia.

A small effect size of workplace bullying [1.37 (0.81–2.31)] was found in Kivimaki's[33] prospective study, which may indicate the significance of emotional abuse. Ruiz-Perez et al.'s[30] retrospective study explored frequent non-partner abuse as a risk factor, finding a medium effect [3.01 (0.84–10.97)], but did not distinguish between emotional, physical or sexual abuse. Post-traumatic stress disorder was found to have a large significant effect on receiving a diagnosis of fibromyalgia one year later [4.4 (3.4–5.9)] in Masters et al.'s[35] retrospective study. Incidence of military sexual trauma was not found to be significant, however, a large association was found between post-traumatic stress and fibromyalgia[28] [$\eta^2 = 0.1842$, $p = 0.0001$], using the Post-Traumatic Checklist-Military (PCL-M[45]).

Additionally, small-medium effect sizes of bipolar disorder [2.8 (2.2–3.6)], panic disorder [3.3 (2.7–4.2)] and memory loss [2.4 (1.9–3.0)] were found to be predictive of a fibromyalgia diagnosis made one year later[35], although there will be a degree of bias in these retrospective results. Out of the total psychiatric diagnoses investigated in this study, post-traumatic stress disorder was found to have the largest effect size.

A small effect size of childhood adversities was reported across all the variables in one prospective study: parental divorce [1.34 (1.05–1.72)], financial difficulties [1.45 (1.18–1.77)], serious conflict [1.40 (1.14–1.72)], serious or chronic illness [1.27 (1.05–1.55)], fear of a family member [1.60 (1.28–2.01)] and parental alcohol problems [1.25 (1.02–1.53)][36].

3.4.2. Occupational Factors

Three studies explored the impact of employment on the risk of developing fibromyalgia, ranging from no effect, small-medium and medium-large effect size[29–31]. The no effect finding by Choi et al.[31] was reported in a higher rated prospective study, however, generalisability of findings may be limited as the sample only comprised of members of the Adventist Church. The effect sizes of employment found

in two other studies[29,30] were reported in retrospective studies. Due to study design, inferences cannot be made from these studies about the timeline of events and cannot be used to form conclusions about employment as a risk factor, only that there is a level of association. Unemployment was investigated as an additional factor in these two studies, with both reporting a non-significant result[29,30]. Low income was not found to be a significant risk factor across three methodologically weaker studies[28–30].

Kivimaki et al.'s[33] prospective study investigated the effect of work stress on the incidence of fibromyalgia, using the Harris Scale[46]. Their findings report a small effect size of high workload [1.03 (0.89–1.19)], low decision latitude [1.00 (0.82–1.24)] and workplace bullying [1.37 (0.81–2.31)] on the risk of developing fibromyalgia. Although this is only one study, this finding is relevant because its conclusions demonstrate the complexity of demographic information in this research; requesting information on employment status may not suffice when there is a varying spectrum of how occupation affects mental wellbeing.

Low education was investigated by seven studies[27,29–32,34,36]. Of these findings, effect sizes ranged from no effect[29,31] to small[32], medium[34] and large[36]. The higher rated quality studies[32,34] were both prospective cohort designs, and therefore more equipped to comment on low education as a risk factor. These studies reported a more modest small and medium effect size of low education ([0.89 (0.85–0.92)] and [2.6 (0.6–11.7)], respectively), indicating that a more conservative effect size should be considered when regarding the relationship between low education and the development of fibromyalgia. Bergman's[27] cross-sectional study did not report an effect size because all the participants in the smaller fibromyalgia group (n=15) belonged to the low education group and could not be compared with a high education group. It should be noted that low education was not assessed by D'Aoust et al.[28], but since all participants in the study were veterans, they all had at least a high school diploma.

3.4.3. Social Factors

Ruiz-Perez et al.'s[30] retrospective study reported social support was related to a lower risk of fibromyalgia [0.47 (0.24–0.93)]. A small-medium sized association was found in a cross-sectional study between lack of social support and the development of fibromyalgia [2.4 (0.6–9.6)][27]. Two studies found no effect of marital status[31,36], however, one study found a medium effect size of marital separation [3.87 (1.93–7.73)][30]. It should be noted that enquiry into marital separation has a different emotional quality to asking about overall marital status. In Varinen's et al.'s[36] study, single, divorced and widowed were all grouped into the same category. Ruiz-Perez et al.[30] also found a medium effect size of being married [4.07 (2.46–6.75)], however, the purpose of this study was to investigate violence against women in the context of fibromyalgia, and 34.3% of fibromyalgia cases had disclosed intimate partner abuse.

A small effect size was found for residence location [2.24 (0.71–7.05)] in Moukaddem et al.'s[29] retrospective study; those living in an urban environment were more likely to have fibromyalgia than those living in a rural environment. Bergman's[27] cross-sectional findings illustrated a medium effect size of immigration [3.6 (0.8–16.6)] and a very large effect size of poor housing [18.1(1.9–168.6)] on the development of fibromyalgia. An effect size for socioeconomic status was not calculated because all the participants in the smaller fibromyalgia group belonged to the low socioeconomic status group.

Bergman[27] also enquired about an immediate family history of chronic pain and reported a large effect size [6.2 (1.8–21.0)]. He suggested that although there may be a genetic component to this result, there may also be an effect of social environment and the modelling of coping strategies around pain behaviour.

4. Discussion

17 potential psychosocial risk factors were identified across the 10 included studies in this systematic review. They were grouped under the following categories: psychological (anxiety, depression, distress, stress, post-traumatic stress, abuse, childhood adversities), occupational (work stress, employment, low income, low education) and social (social support, marital status, immigration, poor housing, residence location and family history).

The most valid conclusions about risk factors are drawn from cohort studies that utilise prospective longitudinal designs. In order for a variable to be considered a risk factor, studies are required to establish a correlation that predates the diagnosis of fibromyalgia[23]. Five of the included studies in this review used this method[31–34,36] and, therefore, their conclusions can be held with greater confidence than the retrospective or observational associations drawn from the other studies. These results show that depression, anxiety, childhood adversity, work stress and low education are risk factors for developing fibromyalgia.

Although research into psychosocial risk factors for specifically fibromyalgia is scare, these results support the existing evidence base around chronic widespread pain. Measures of anxiety and depression have been implicated as risk factors[47], as have adverse childhood events[48,49], psychosocial factors in the workplace[50] and low education[51]. Education and related sociodemographic variables are closely linked to health outcomes[52], therefore, it is surprising that low income and unemployment were not found to be significant risk factors. These variables, along with the current review's results of the large effect of poor housing[27], may come under the wider umbrella of socioeconomic status. Those of low socioeconomic status are three times more likely to develop chronic widespread pain, although these relationships were explained in part by poor mental health and lifestyle factors[53]. Similarly, other studies have explained the relationship via adverse behavioural and social circumstances, such as smoking and low education[54] and the impact of living in high social threat environments on adjustment to chronic pain[55]. The negative effects of these factors are even more

pronounced in populations of immigrants with pain[56,57], which conveys the combined impact of multiple stressors in a situation exacerbating chronic pain conditions.

Being diagnosed with memory loss or a psychiatric illness, especially PTSD, was found to predict a diagnosis of fibromyalgia one year later, although retrospective data is flawed by recall bias. There is a relationship between psychiatric distress and fibromyalgia (see Bradley[58] for a review), but Aaron et al.[59] raise an interesting point about this relationship. They demonstrated that 'non-patients' with fibromyalgia had a lower incidence of psychiatric history than patients with fibromyalgia, and were in fact similar to that of controls, which suggests that pre-morbid mental health difficulties are not inherently linked to fibromyalgia. Differences in distress scores no longer existed after controlling for pain threshold and fatigue. They concluded that a history of psychiatric illness may be more related to the manner in which healthcare is sought.

The results of this study have shown that lack of social support, immigration, residence location, family history, abuse and post-traumatic stress were all found to be significantly associated with fibromyalgia. Cross-sectional and case-control studies cannot make statements about the predictive nature of risk factors in the absence of time-related data. Grimes and Schulz[60] note that there may be a difference in motivation for identifying a cause for illness between cases and controls, which results in a higher recall rate for cases. These issues have been considered throughout this review and results from these studies have been conceptualised as associations instead of risk factors, to differentiate their value in predicting fibromyalgia. The relationship between abuse, PTSD and fibromyalgia has been well documented in literature and reviewed elsewhere[18,19]. A lesser researched area is that of the aforementioned social and environmental factors.

Higher levels of social support are related to more active coping strategies in patients with chronic pain[61], and larger support networks have been linked to better symptom management in fibromyalgia. It is, however, the quality of social support that is associated with lower psychological distress[62]. This suggests that closed questions about the availability of social support is not the best way to explore

this topic, since the quality of social support is more valuable than quantity. Central to this idea is the ability to elicit support effectively, in order to be able to successfully use social support networks. Di Tella et al.[63] demonstrated a negative relationship between alexithymia, distress and the ability to employ efficient coping strategies and seek social support in patients with fibromyalgia. Those who are unable to articulate their internal world and own needs to others may lead to underutilised social support networks, even if they are present and available.

Previous research has highlighted the significance of socially and behaviourally learned models of pain in families[64], separate from genetic influences[65]. Taking a family history is important from this perspective because this line of enquiry is typically used in healthcare to ascertain genetic linkage and genetic risk, and less so for establishing behavioural and attitudinal baselines around pain conditions. Family systems may contribute to the internalisation of bias and stigma surrounding chronic pain[66], if unhelpful generational and cultural beliefs are being modelled and passed on.

Studies varied in the method used to ascertain fibromyalgia. Five studies used the ACR-1990 criteria, three relied on self-report measures, one used ICD-9 codes and one used the LFESSQ. Two utilised medical examination and two relied on medical testing to further verify the presence of fibromyalgia. Katz et al.[67] demonstrated moderate concordance between use of the ACR-1990, survey, clinical methods in ascertaining fibromyalgia, suggesting that, in the absence of a gold standard, the various methods are all still valid. They define fibromyalgia as a 'trait' instead of a 'state' diagnosis, meaning that a person can be considered to have a degree of the condition even if they do not meet all the criteria requirements at a certain point in time. Sarzi-Puttini et al.[68] theorise that the tenderness criteria in the ACR-1990 can be attributed to psychological distress as opposed to pressure pain, which raises questions about internal validity. Newer versions of the criteria have been revised (ACR-2010/2011 and ACR-2016); tender point examination is no longer necessary, and extra consideration has been given to related symptoms, such as depression and headaches[69].

Because study quality was generally found to be good (based on the ratio of positive to negative ratings), the conclusions that can be drawn from this review can be made with greater confidence. The prospective cohort design studies were all found to be of appropriate quality in providing a level of confidence in their results. Six studies[27,29,32,34–36] recruited from population registries and random sampling methods were used to reduce bias. Almost all the studies in this review used logistic regression to predict likelihood of fibromyalgia, which is more accurate in the absence of a sampling bias.

4.1. Limitations and Potential Bias

This review was limited to risk factors identified by published, peer-reviewed studies. Due to limitations in time and resources, non-English and unpublished literature was not included. Publication bias is therefore a limitation as there will be other studies that demonstrate both significant and non-significant results, and exclusion of these studies may overinflate the impact of a given risk factor. Participants in the included studies were predominantly Caucasian, with the exception of one study which was conducted in Lebanon[29], which will limit generalisability to the wider population.

Comments on gender are limited within this review because participants in the included studies were predominantly female, with some only recruiting female participants. Obviously, this has significant implications for generalising results, but this may be a reflection of problematic historical issues in diagnostic criteria. Fibromyalgia is more commonly associated with women[6], however, clinical biases in the old ACR-1990 diagnostic criteria appear to discriminate against gender. Non-clinical female participants have been shown to have a lower threshold for pressure pain across tender point areas[70], which demonstrates that women are more likely to fulfil criteria according to the ACR-1990. Furthermore, research has shown that sociodemographic risk factors for women may not apply to men, and women have a longer illness duration[51], suggesting that there may be varying illness profiles between women and men.

This review specifically focused on fibromyalgia instead of broadening the search to chronic widespread pain; some clinicians and academics believe the two conditions overlap to such a degree that the validity of the diagnosis is questioned[11]. It may also be the case that many participants in chronic widespread pain research have undiagnosed or misdiagnosed fibromyalgia, thus blurring the boundaries in the first instance. This review also restricted the focus to fibromyalgia excluding co-morbidities (e.g. arthritis), which will limit the generalisability of the results to a less complex population.

Heterogeneity of outcome measures across the included studies limit the strength of the conclusions that can be drawn; results were too diverse to synthesise. Meta-analysis was not possible and most outcome measures only had one or two studies investigating the same variable. Low education was the most commonly studied factor in this review, and due to the varying quality of the results, a conservative estimate of effect size was suggested.

Overall ratings of quality were based on the percentage of positive ratings out of all items available for each study. These percentages are broadly equivalent and can be comparable, except for studies that rated 'not applicable' for certain quality criteria items[27–30,35]. An arbitrary categorical rating (e.g. 'good' and 'poor') was not given to each study because of the heterogenous nature of study design and outcomes. Percentages allow for a fairer comparison of bias, however, the limitation with using percentages is the assumption that all items are equal in quality and therefore should be given the same weight. The percentages stated are therefore arbitrary and are only used to determine which studies are qualitatively more biased in comparison to the possible available total score. The second reviewer only independently assessed 3 of the included studies, therefore, bias may be present in the quality ratings of the remaining 7 studies.

Two of the included ten studies analysed secondary data[28,29]. Both of these studies were rated lower in quality and this may be a reflection of the study design not being tailor-made for the research question. These studies will be subject to selection bias as participants have been handpicked from an

existing pool of participants. This represents another level of non-randomisation, which may not be representative of the wider population and runs the risk of overinflating results.

4.2. Conclusion

This review has highlighted some problematic implications for this area of research. There is an intrinsic selection bias within the diagnostic criteria for fibromyalgia at the clinical level. Although newer versions of the ACR have been proposed to overcome practical limitations and bias against gender, many newer empirical studies continue to use the old criteria. Research into risk factors need to be based on prospective cohort designs if they are to make valid conclusions about the predictive effect of variables. There is problematic heterogeneity across the definition of outcome measures and variability across the validated measures used to assess these. Despite these limitations and in the context of diverse results, this review has demonstrated that depression, anxiety, childhood adversity, work stress and low education are risk factors for the development of fibromyalgia. Lack of social support, immigration, urban residence, family history, abuse and post-traumatic stress were all found to be significantly associated with fibromyalgia. There will be an element of interrelatedness across these variables; research into the moderating and mediating factors will be important to further disentangle these relationships. This review sits in line with previous research into the risk factors for chronic widespread pain and supports the few existing reviews into the risk factors for fibromyalgia.

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Chapter 2: Empirical Study

Compassion-Focused Therapy for adults with chronic pain: the mediating role of self-compassion, psychological flexibility and psychological inflexibility on improvement across group outcomes

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Abstract

Objective: Psychological approaches to chronic pain so far have focused on Cognitive Behavioural Therapy (CBT) and Acceptance and Commitment Therapy (ACT). There is limited research in Compassion-Focused Therapy (CFT) for chronic pain. This study aims to 1) evaluate the suitability of a CFT Pain Management Programme (PMP) for adults with chronic pain and 2) explore self-compassion, psychological flexibility and psychological inflexibility as potential mediators of improvement in outcome.

Methods: Participants were patients who completed the 11-week PMP at the NHS Lothian Chronic Pain Service between February 2018 and March 2019 (n=122). Participants completed the following outcome measures at pre-group (week 1), mid-group (week 6) and post-group (week 11): The Brief Pain Inventory, Hospital Anxiety and Depression Scale, Self-Compassion Scale, Multi-Dimensional Psychological Flexibility Inventory and the Warwick-Edinburgh Mental Wellbeing Scale. One-way ANOVAs were used to evaluate the efficacy of the intervention, along with multiple regressions to perform mediation analyses.

Results: Statistically significant improvements were demonstrated in measures of pain interference, anxiety, depression, psychological flexibility, psychological inflexibility, self-compassion and mental wellbeing by the end of the PMP. The largest improvements were found to occur in the second half of the PMP. Self-compassion was shown to mediate improvements in pain interference, whereas psychological flexibility and psychological inflexibility were shown to mediate improvements in depression and mental wellbeing. Neither predictor variable mediated improvements in anxiety.

Discussion: This study provides evidence for the use of CFT as a group intervention for chronic pain. Psychotherapies already share conceptual overlaps; clinical resources can be better used by integrating complementary approaches to maximise the benefits for our patients.

Keywords

Chronic pain; compassion-focused therapy; self-compassion; psychological flexibility; psychological inflexibility; mediators; pain management programme

Abbreviations

ACT	Acceptance and Commitment Therapy
BPI-SF	Brief Pain Inventory (short-form)
CBT	Cognitive Behavioural Therapy
CFT	Compassion-Focused Therapy
HADS	Hospital Anxiety and Depression Scale
MPFI-SF	Multidimensional Psychological Flexibility Inventory (short-form)
PMP	Pain Management Programme
SCS-SF	Self-Compassion Scale (short-form)
SWEMWBS	(short-form) Warwick-Edinburgh Mental Wellbeing Scale

Word Count: 8,119

1. Introduction

1.1. The Impact of Chronic Pain

Pain is considered to be chronic when it has lasted for longer than 3-6 months, past its primary function of nociception[1]. A systematic review by Fayaz et al.[2] reported the prevalence of chronic pain to be between 35.0% and 51.3% across the UK, increasing in prevalence with age and with a greater likelihood in women. In 1998, the socio-economic costs of back pain in the UK were estimated to be £1.6 billion, taking into account healthcare usage, production losses and informal carers[3]. Evidently, chronic pain is a major health issue for both the individual and the wider systems around the individual. Research shows that chronic pain has an extensive, negative impact on physical health, psychological wellbeing, daily functioning, relationships and occupation[4,5].

In the process of learning to live with chronic pain, sufferers may have experiences of being disbelieved by family, friends and health professionals, struggle with their own beliefs of being a burden on their loved ones and feel disappointment at perceived inability to fulfil previously held roles in the family and workplace[6,7]. Chronic pain can become stigmatic through the internalisation of such experiences[8], and in conjunction with debilitating physical symptoms, it has a profound impact on the sense of self. The intensity of the pain is often not the main issue[9]; interpretations of pain can perpetuate distress, for example, in the negative beliefs and learned associations that someone may hold about their pain[10]. Because negative cognitions and emotions are activated by pain-related difficulties, multi-disciplinary treatments for chronic pain seek to manage these internal experiences and modify behaviour, rather than eliminate the physical sensation of pain.

1.2. Current Treatment Models in Chronic Pain: CBT

Alongside education and physical exercise, Cognitive Behaviour Therapy (CBT) and Acceptance and Commitment Therapy (ACT) are used across multidisciplinary pain management programmes in the treatment of chronic pain (as described in SIGN Guideline 136[11]).

CBT for chronic pain uses the biopsychosocial model to identify and address the distressing appraisals, distorted cognitions and maladaptive behaviours that exacerbate pain. Techniques such as graded activation and exposure are used to help achieve sustainable levels of activity and reduce avoidance[12,13]. A Cochrane review in 2012[13] involving 42 studies reported small effects on disability and catastrophising in comparison to active controls. No such effect was found on pain or mood. Moderate effects on pain disability, mood and catastrophising were found when compared to wait list controls, however, the use of wait list controls exaggerate apparent efficacies[14], with a danger of overstating the evidence base for CBT for chronic pain. There was evidence to suggest that gains in mood and catastrophising were maintained at six months post-treatment. The authors concluded that further randomised controlled trials reporting on mean treatment group differences will not lead to scientific or clinical progress, and instead, research should focus on *how* CBT works.

The philosophy of randomised controlled trials does not translate well into psychotherapy research because it is difficult to isolate an active component[15]. Psychotherapies share commonalities such as therapeutic relationships, collaboration and acceptance of psychological and cultural explanations of distress[16], and even tightly controlled trials face difficulties with generalisation because of unrealistic exclusion criteria and fidelity to treatments[15]. Gaudiano[17] notes that more attention should be focused on the mechanisms of action as opposed to pitting separate treatments against each other and drawing conclusions about their efficacy based on differences across outcomes.

Turner et al.[18] identified key mediators behind the effects of CBT: change in pain beliefs, catastrophising and self-efficacy, in the context of chronic temporomandibular disorder pain and

disability at one year. Change in pain beliefs was found to be the mediator with the greatest effect on outcomes of pain and activity interference, although there was a degree of relatedness between the mediators. Self-efficacy was found to be independent of the other process variables. Pain catastrophising was also identified as a mediator in similar studies[19,20], as was internal locus of pain control[19]. From these results, it is clear that the active ingredients in CBT are processes that are not unique to CBT[21]; such therapeutic targets are of interest in other psychological therapies, although the components may be conceptualised from a different perspective.

1.3. Current Treatment Models in Chronic Pain: ACT, Psychological Flexibility and Psychological Inflexibility

ACT aims to help people move towards valued behaviour and increase willingness to accept and tolerate undesirable internal experiences. Unlike CBT, ACT does not attempt to alter the content of negative cognitions; instead, the focus is to manage responses and make behavioural adjustments in a manner that is consistent with a person's values. This lessens the influence of behaviour that is driven by pain-related avoidance, which contributes to disability. A systematic review by Hughes et al.[22] examined 11 trials of ACT for adults with chronic pain, finding significant medium to large effect sizes for measures of acceptance and psychological flexibility, although this was mainly in comparison to treatment as usual controls. Another review by Veehof et al.[23] included 22 studies and reported medium effect sizes of ACT and mindfulness-based treatments on pain intensity, mood, physical wellbeing and quality of life. The authors question the validity of using pain intensity as an outcome measure when neither ACT nor CBT focus on reducing pain intensity. They recommend that future studies include other pain measures, such as pain interference.

The key elements of ACT are psychological flexibility and inflexibility[24]. Psychological flexibility can be defined as adaptable responses to negative internal and external events, which promote wellbeing; and psychological inflexibility can be defined as fixed responses to negative internal and external

events, which are associated with psychological distress[25]. Cross-sectional evidence demonstrates that psychological inflexibility is linked to anxiety, depression and wellbeing[26]. The six-factor theory of psychological flexibility (the Hexaflex model[27]) is made up of six components: contact with the present moment, values, committed action, self as context, defusion and acceptance[25]. The six-factor theory of psychological inflexibility is made up of six further components: lack of contact with the present moment, lack of contact with values, inaction, self-as-context, fusion and experiential avoidance[25].

Vowles et al.[28] performed correlation and regression analyses and reported significant relationships between all aspects of psychological flexibility and measures of disability, emotional functioning, pain acceptance and valued activity. Four key process variables of psychological flexibility were investigated by McCracken and Gutierrez-Martinez[29]: pain acceptance, values-based action, psychological acceptance and mindfulness. General acceptance was found to show the largest effect size, predicting gains in outcome more so than those accounted for by pain acceptance. Psychological flexibility was also shown to moderate outcomes of pain interference on an internet-based ACT for chronic pain[30]. In summary, psychological flexibility and inflexibility appear to be a highly relevant processes in understanding and influencing responding to chronic pain, leading to improved function across a range of parameters.

1.4. CFT and Self-Compassion

Compassion-Focused Therapy (CFT) was developed for individuals who struggle with shame and self-criticism[31], both of which can be conceptualised as examples of distressing private experiences in the ACT model. It aims to promote a compassionate relationship with the self, drawing on the ability to view distressing experiences with kindness, understanding and shared humanity[32]. Shame involves a negative evaluation of the *self*, unlike guilt, which involves a negative evaluation of *behaviour*[33]. This is especially relevant in chronic pain, where people are faced with pervasive internal and external negative social appraisals, which are adopted into the self. CFT is based on evolutionary functional

analysis and is centred around emotion regulation via the three circles model: the threat (fight or flight), drive (resource-seeking) and soothe (nurturing attachment) systems. From this perspective, an impoverished soothe system results in emotional dysregulation and CFT asserts that increasing self-compassion is fundamental to reassurance, safety and wellbeing[31]. A systematic review in 2014[34] included 14 studies of CFT, showing favourable results for mood disorders and for those high in self-criticism. The evidence was insufficient, however, to show that CFT was superior to other approaches such as CBT, although using CFT jointly with CBT increased efficacy. No studies in the review explored self-compassion as a mediator in the relationship between intervention and outcome.

The positive influence of self-compassion has already been investigated across a range of long-term health conditions, such as diabetes[35] and cancer[36]. Wren et al.[37] found self-compassion to be a significant predictor of mood, negative pain beliefs and disability related to pain. This cross-sectional study indicated that self-compassion may be significant in predicting pain adjustment, but can only comment on association and not causal relationships. The authors suggest that future research in this area could examine interventions specifically designed to promote self-compassion. Marshall and Brockman[38] reported self-compassion to significantly correlate with processes of psychological flexibility, and self-compassion actually predicted mental wellbeing over and above psychological flexibility. This indicates that combining these therapies may result in improved treatment outcomes. This study was, however, conducted on a non-clinical population which may limit generalisability. Empirical research examining links between these two constructs is limited.

A recent exploratory study by Penlington[39] evaluated a compassion-focused group for chronic pain within a routine clinical setting. This was an 8-week programme of mindfulness and loving-kindness exercises, showing small to moderate effect sizes of improvements in pain distress and depression, and moderate to large effect sizes of improvements in anxiety. Small improvements were found in measures of pain intensity and self-efficacy. Although lacking in internal validity, as an exploratory study, these results reflect promising external validity due to its clinical setting and realistic participant

recruitment. Other smaller studies have derived similar results for compassion cultivation for chronic pain[40] and for loving-kindness meditation for chronic low back pain[41].

The previous sections have been segregated by therapeutic orientation for the purpose of structure and clarity, but there is clearly a large degree of commonality between concepts and constructs. Self-acceptance can be easily conceptualised as self-kindness. Acts of psychological inflexibility, such as avoiding negative experiences and fusing with harmful narratives, are really acts of self-rejection and self-criticism. Conversely, acts of psychological flexibility, embracing and being open to all parts of the self and choosing actions based on personal integrity, these are inherently kind, supportive and self-validating acts. The evidence base reflects these conceptual overlaps and, furthermore, suggest that ACT and CFT can be integrated for maximum clinical benefit.

1.5. Rationale

There is a need for evidence-based answers to explain why and how psychological interventions are successful[42]. Randomised controlled trials are inadequate for comparing models and multi-modal treatments cannot separate the contribution of different principles. For example, comparisons between an ACT and a CBT pain management programme showed no differences in improvements in pain interference, depression, anxiety and quality of life[43]. Designing trials to isolate the influence of different principles would be expensive and time-consuming; a different strategy is to test mediation hypotheses. CFT offers a complementary approach to be used alongside current interventions, targeting the frequent feelings of shame and self-criticism in the process of adjusting to chronic pain. Research suggests that there is theoretical basis for the use of CFT in chronic pain, and a strong correlation between self-compassion and psychological flexibility has already been established. Gaining insight into the direction of these relationships and using these concepts to optimise treatment targets should be the overall objective in this area of research.

1.6. Study Hypotheses

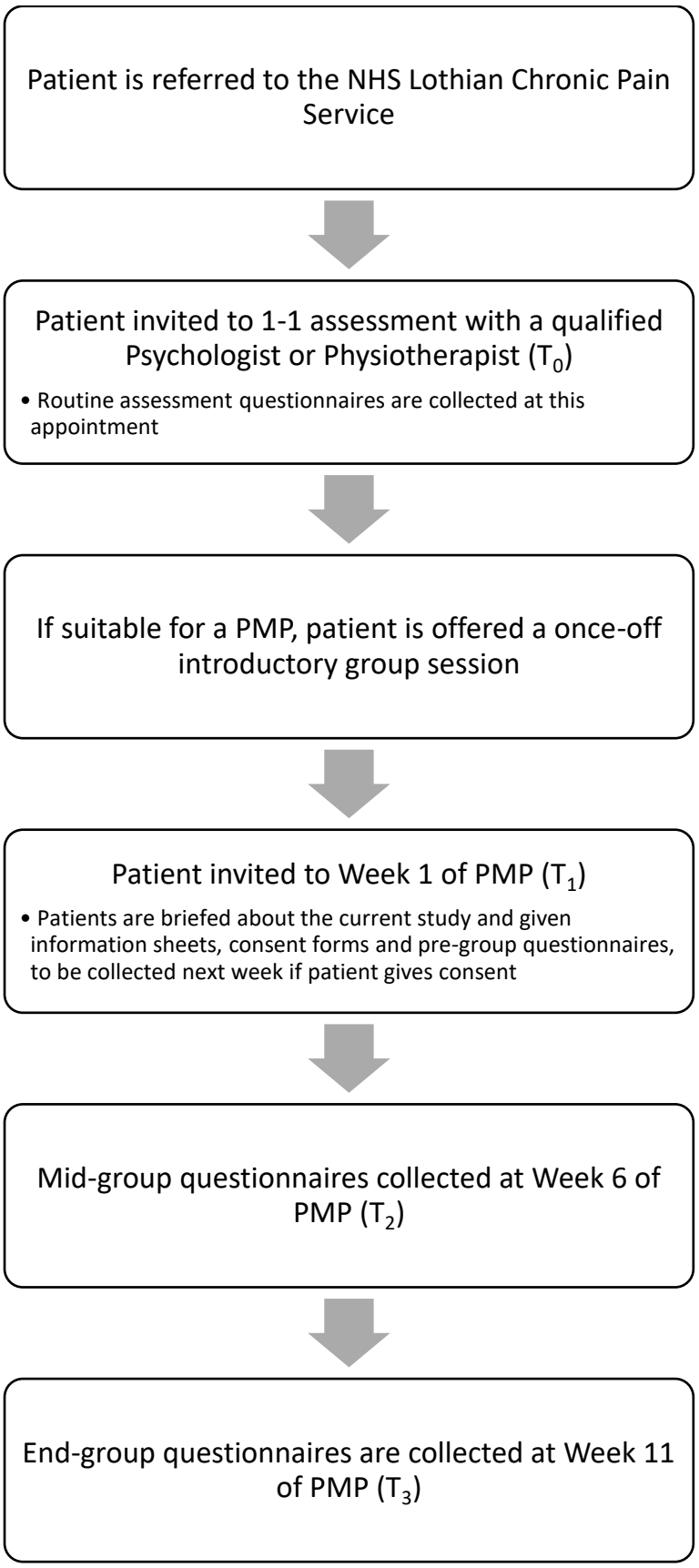
1. An 11-week Compassion-Focused Therapy Pain Management Programme (PMP) group intervention will significantly improve measures of pain interference, anxiety, depression, psychological flexibility, self-compassion and psychological wellbeing.
2. Self-Compassion, Psychological Flexibility and Psychological Inflexibility will mediate the improvements in pain interference, anxiety, depression and psychological wellbeing from Week 1 to Week 11.

2. Methodology

2.1. Participants

Participants were adults with chronic pain who attended a PMP at the NHS Lothian Chronic Pain Service between February 2018 and March 2019. This centralised outpatient service is located in Edinburgh, receiving referrals mainly from General Practitioners, a multidisciplinary pain clinic and secondary care consultants. Potential PMP patients were assessed for suitability by the clinical team (Clinical/Counselling Psychologists and Physiotherapists) during a routine one-to-one assessment upon referral to the Chronic Pain Service. Patients were eligible for the current study if they were over the age of 18, suffered from chronic pain lasting a minimum of three months, and were of adequate English fluency, sufficient for participation in a group. Patients were not eligible for the study if they were unable to provide consent (as defined by the Five Statutory Principles of the Mental Capacity Act[44]). If a patient was deemed to be suitable for a PMP, an introductory group session was offered, followed by invitation to an upcoming 11-week PMP. Participants were briefed about the study during the first week of the PMP, with questionnaires and consent forms to be completed and returned the following week if consent was given. Figure 2 depicts the journey of a PMP patient through the service and the research.

Figure 2 Participant flow through PMP and recruitment for research



2.2. Power and Sample Size

Fritz and MacKinnon[45] propose guidelines for recommended sample sizes in order to detect mediation effects, informed by existing literature. Research into self-compassion and chronic pain is currently limited, therefore, sample size calculations were based on correlations between pain interference and psychological flexibility (*r* values between 0.37 and 0.46[46]). Other findings of relevance include correlations between psychological flexibility and outcomes of group interventions for chronic pain (*r* values between 0.33 and 0.55[29]) and between psychological flexibility and psychological functioning (*r* values between -0.47 and -0.51[47]). Hayes et al.[27] conducted a meta-analysis on the correlations between measures of psychological flexibility and psychopathology, with the vast majority of the included studies demonstrating large effect sizes between psychological flexibility and anxiety, depression and quality of life measures. Since the literature demonstrates medium to large correlational sizes across the α and β pathways of the mediation model, it was determined that a sample size of 53-71 participants would be required to detect an effect with .8 power.

2.3. Procedure

A small subset of the questionnaires was collected at assessment (T_0), prior to starting the PMP; this was the waiting list period. Over the course of the PMP, five outcome measures were collected at three timepoints: pre-group (T_1), mid-group (T_2) and post-group (T_3) (see Figure 2). Information sheets, consent forms and pre-group measures (Appendix 6-8) were given out at the start of the group (week 1), to be completed and returned the following week; participants were given a full week to consider their voluntary involvement in the research. Mid-group measures were collected at week 6 and post-group measures were collected at week 11. Those who did not give consent were asked to complete the outcome measures at week 1 and week 11, as the service routinely collects the same information for service evaluation and patient feedback.

2.4. Outcome Measures

2.4.1. Pain

The Brief Pain Inventory (short form, BPI-SF[48]) is an 11-item measure designed to capture two aspects of pain: pain interference with daily living (e.g. "relations with other people") and pain severity (e.g. "at its worst in the last 24 hours". These two distinct dimensions have been confirmed through factor analysis. Responses to items on this measure range from 0 (does not interfere) to 10 (completely interferes) on the pain interference subscale and 0 (no pain) to 10 (pain as bad as you can imagine) on the pain severity subscale. The BPI-SF shows stable test-retest reliability and high internal consistency, with Cronbach's α ranging from .80 to .92[49]. In this sample, the pain intensity subscale showed high internal consistency (Cronbach's α = .86/.92/.92 for pre/mid/post timepoints); and the pain interference subscale also showed high internal consistency (Cronbach's α = .87/.93/.91 for pre/mid/post timepoints). The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT[50]) recommends that all chronic pain research should include outcomes in pain interference and pain severity.

2.4.2. Anxiety and Depression

The Hospital Anxiety and Depression Scale (HADS)[51] is a 14-item measure of the symptoms of anxiety (7 items) and depression (7 items) in individuals with physical health issues. Each of the items are scored from 0 to 3, where a higher score depicts greater frequency or intensity of the described symptom over the last week (e.g. "I get sudden feelings of panic" and "I have lost interest in my appearance"). Anxiety and depression are rated separately, each allowing for a minimum score of 0 or a maximum score of 21. Bjelland et al.[52] reviewed 747 papers using the HADS and demonstrated a two-factor structure (i.e. anxiety and depression), with a high level of internal consistency for both the anxiety (Cronbach's α = .83) and depression (Cronbach's α = .82) subscales. In this sample, the anxiety subscale showed high internal consistency (Cronbach's α = .82/.89/.87 for pre/mid/post timepoints);

and the depression subscale also showed high internal consistency (Cronbach's α = .82/.85/.82 for pre/mid/post timepoints). Michopoulos and authors (2008)[53] demonstrated a high test-retest reliability of .94 over a 20-day period.

2.4.3. Psychological Flexibility and Inflexibility

The Multi-Dimensional Psychological Flexibility Inventory (short form, MPFI-SF[25]) is a 24-item measure assessing openness to negative experiences such as thoughts and feelings (psychological flexibility) and fixed ways of reacting to negative experiences (psychological inflexibility). 12 items measure psychological flexibility and 12 items measure psychological inflexibility. The MPFI aims to measure all the components of the Hexaflex model, and has been shown to demonstrate both discriminant and convergence validity[25]. Response to items range from 0 (never true) to 6 (always true) of items in the context of the last two weeks (e.g. "I stuck to my deeper priorities in life" and "negative feelings often trapped me in inaction"). The MPFI demonstrates an excellent level of internal consistency for both the flexibility and inflexibility subscales (Cronbach's α = .88 to .91 across a range of demographic groups)[25]. In this sample, the flexibility subscale showed good internal consistency (Cronbach's α = .78/.93/.94 for pre/mid/post timepoints); and the inflexibility subscale also showed good internal consistency (Cronbach's α = .70/.87/.87 for pre/mid/post timepoints). This supersedes the levels of internal consistency found for the Acceptance and Action Questionnaire[27], the Acceptance and Action Questionnaire–II[54] and the Avoidance and Fusion Questionnaire[55], which are the most common tools used in this area[25].

2.4.4. Self-Compassion

The Self-Compassion Scale (short form, SCS-SF[32]) is a 12-item measure designed to assess a person's kindness and understanding towards themselves during difficult times. Responses to these items (e.g. "I try to see my failings as part of the human condition") are indicated on a Likert scale, ranging from 1 (almost never) to 5 (almost always). The SCS-SF has a strong correlation with the long form measure,

and factor analysis has validated the six-factor model, in addition to the single higher-order factor of self-compassion[56]. The SCS-SF shows high internal consistency (Cronbach's α = .86[56]) and good test-retest reliability over three weeks (scores of at least .8 across all subscales)[32]. In this sample, the SCS-SF showed good internal consistency (Cronbach's α = .85/.86/.72 for pre/mid/post timepoints).

2.4.5. Mental Wellbeing

The short-form Warwick-Edinburgh Mental Wellbeing Scale (SWEMWBS[57]) is a 7-item measure reporting on subjective positive mental wellbeing and psychological functioning over the last two weeks, validated for use in a British adult population. It aims to cover a broad range of positive mental health concepts (e.g. "I've been feeling useful" and "I've been feeling close to other people") but does not include spirituality or socioeconomic factors. Each of the items on the measure require a response on a Likert scale, from 1 (none of the time) to 5 (all of the time). This yields a minimum score of 7 and a maximum score of 35. The SWEMWBS has a good level of internal consistency (Cronbach's α = .84 in Norway and .86 in Sweden[58]). In this sample, the SWEMWBS showed high internal consistency (Cronbach's α = .83/.88/.91 for pre/mid/post timepoints). There is no information available on test-retest reliability (according to its website https://www.corc.uk.net/outcome-experience-measures/short-warwick-edinburgh-mental-wellbeing-scale), however, the long-form WEMWBS's test-retest reliability of .83 demonstrated stability after one week[57].

2.5. Intervention

The group intervention took place over 11 consecutive weeks, 3 hours per session. Week 6 and Week 11 were individual one-to-one sessions, with one of the two group facilitators. Two to three groups started each month, with 6 groups (at different stages) running each week. Groups were booked to 17 patients per group and were facilitated by a qualified Psychologist and Physiotherapist. Psychology facilitators participated in four days' CFT training facilitated by Dr Chris Irons, Clinical Psychologist, from the Compassionate Mind Foundation. Table 3 below illustrates the weekly session content across

the 11-week group intervention. Participants were given workbooks and clinicians referred to slides and session notes throughout the group. All psychology facilitators received regular individual and group supervision from qualified Clinical Psychologists working in the service.

2.6. Ethics

Ethical approval was sought through the NHS Integrated Research Approval Service and a Research Ethics Committee granted approval on 9th February 2018. (REC reference 17/EM/0465) (Appendix 4). This included review of participant information sheets, consent forms and outcome measures (Appendix 6-8).

Table 3 Session content of the CFT group per week

Week	**Session Content**
1	Introduction and group guidelines; pain education; adjustment
2	Movement and pacing; introduction to CFT: tricky brain
3	Three circles model of CFT; pacing; pain, stress and coping
4	Goals; compassion and mindfulness
5	Compassionate thoughts; sleep hygiene
6	Individual review with a group facilitator
7	Pain and relationships *(a friend or family member can attend this week)*; flare-up planning
8	Functional movement; compassionate imagery (other); endings
9	Compassion and adjustment; compassionate imagery (self)
10	Maintaining progress; compassionate letter writing
11	Individual review with a group facilitator
N.B.	*Physical exercise and CFT exercises are incorporated into every session from Week 2*

2.7. Statistical Analyses

Analyses were completed using SPSS 24. Missing data for those who did not complete the PMP was imputed using last observation carried forward (LOCF). Little's Missing Completely at Random (MCAR) test indicated that the data was missing at random: $\chi 2$ (475, N = 122) = 317.402, p = 1.000. Missing data across individual questionnaires (i.e. unanswered questions on completed questionnaires) was imputed using Expectation Maximisation (EM), where missing data was <10% and normally distributed. The percentage of missing data across individual questionnaires varied from 0.8% to 8.2%, with a few exceptions: 14.8% of data was missing across assessment (T_0) questionnaires, missing data from pre-group (T_1) psychological flexibility (MPFI) was 22.1% and missing data from mid-group (T_2) psychological flexibility (MPFI) 17.2%. Listwise deletion was employed where EM was not appropriate. This was deemed to be a suitable alternative since data was missing at random and the sample size was large enough to remain adequately powered, as recommended by Cheema[59].

Assumptions of normality were met since skewness was found to be between -0.842 and 0.624 across all levels of the outcome measures at each timepoint; and kurtosis was between -0.858 and 0.556. These values are between the minimum and maximum allowable values of -1.00 and 1.00 for an ANOVA and regression[60]. A one-way ANOVA was used on participant demographics and completion status (full completers, mid-completers and non-completers), and on pre-group outcome measures across different levels of completion status, in order to test the equivalence of completers versus non-completers. Appropriate corrections were used where Mauchly's Test of Sphericity was violated (Greenhouse-Geisser when $\varepsilon < 0.75$ and Huynh-Feldt when $\varepsilon > 0.75$). A repeated measures ANOVA with post-hoc Bonferroni corrections was used on the assessment, pre-, mid- and end-group outcome measures to test the efficacy of the PMP.

Mediation analyses were performed using guidelines recommended by Judd, Kenny and McClelland[61] for within-subjects mediation. All scores were scaled in the same direction for this purpose. An analysis

of standard residuals highlighted two outliers, which were removed. Following this, all assumptions were met.

3. Results

Out of the 122 participants, 18 (14.7%) dropped out of the intervention before the mid-point and 14 (11.5%) dropped out of the intervention after the mid-point. In total, 32 participants did not complete the PMP (an attrition rate of 26.2%). No significant differences were found across participant demographics and completion status (Table 4). No significant differences were found between scores of pain intensity, pain interference, anxiety or depression between assessment (T_0) and pre-group (T_1) (Table 5), nor across pre-group outcome measures at different levels of completion status (Table 6). The repeated measures ANOVA showed significant improvement in measures of pain interference, anxiety, depression, psychological flexibility, psychological inflexibility, self-compassion and mental wellbeing by the end of the PMP (Table 7). There was no significant difference in scores of pain intensity by the end of the group.

The average level of anxiety moved from the 'moderate' range to the 'mild' range by the end of the PMP, according to clinical cut-off scores on the HADS[51], whilst depression remained in the 'mild' range. Those who did not complete the PMP scored an average of 'moderate' depression at pre-group, whereas those who completed the PMP scored an average of 'mild' depression at pre-group, although this distinction was not deemed to be statistically significant. The average score of self-compassion was in the 'moderate' range[32] before the PMP started, and remained in this range by the end of the group, even though the improvements were considered to be statistically significant.

Table 4 Participant demographics and significance levels by completion status

	Completer (n=90)	**Non-Completer** (n=32)	***p***
Gender			0.279
Female	74 (82.2%)	29 (90.6%)	
Male	16 (17.8%)	3 (9.4%)	
Age			0.274
16-24	1 (1.1%)	1 (3.1%)	
25-34	13 (14.4%)	6 (18.8%)	
35-44	23 (25.6%)	9 (28.1%)	
45-54	24 (26.7%)	10 (31.3%)	
55-64	24 (26.7%)	3 (9.4%)	
65-74	4 (4.4%)	3 (9.4%)	
75-84	1 (1.1%)	–	
Duration of pain			0.755
<1 year	5 (5.6%)	–	
12-17 months	5 (5.6%)	1 (3.1%)	
18-24 months	2 (2.2%)	2 (6.3%)	
2-3 years	5 (5.6%)	2 (6.3%)	
4-5 years	9 (10.0%)	3 (9.4%)	
6-10 years	17 (18.9%)	7 (21.9%)	
11-20 years	17 (18.9%)	6 (18.8%)	
21+ years	9 (10.0%)	2 (6.3%)	
Missing	21 (23.3%)	9 (28.1%)	
Diagnosis			0.560
Back Pain	33 (36.7%)	9 (28.1%)	
Fibromyalgia	25 (27.8%)	8 (25.0%)	
ME/Chronic Fatigue	3 (3.3%)	1 (3.1%)	
Arthritis	3 (3.3%)	1 (3.1%)	
CRPS	2 (2.2%)	1 (3.1%)	
IBS/Abdominal	2 (2.2%)	–	
Headache/Facial	2 (2.2%)	2 (6.3%)	
No Diagnosis	2 (2.2%)	2 (6.3%)	
Other	7 (7.8%)	2 (6.3%)	
Missing	11 (12.2%)	6 (18.8%)	
Employment			0.452
Full-time	21 (23.3%)	5 (15.6%)	
Part-time	14 (15.6%)	5 (15.6%)	
Voluntary	2 (2.2%)	1 (3.1%)	
Not working due to pain	24 (26.7%)	11 (34.4%)	
Not working for other reason	7 (7.8%)	2 (6.3%)	
Missing	22 (24.4%)	8 (25.0%)	

Table 5 Comparison of study variables between assessment (T0) and pre-group (T1)

Outcomes (n=92)	**Means (SD)**				
	Assessment (T_0)	**Pre-Group (T_1)**	**F**	***p***	***η_p^2***
BPI					
Pain Intensity[SA]	24.34 (6.48)	24.46 (5.69)	0.046	0.830	0.001
Pain Interference[SA]	49.44 (13.44)	48.91 (11.00)	0.249	0.619	0.003
HADS					
Anxiety[SA]	12.00 (4.79)	12.14 (4.22)	0.140	0.709	0.002
Depression[SA]	11.05 (4.12)	10.66 (3.60)	1.221	0.272	0.013

[SA]Sphericity assumed

Table 6 Comparison of study variables at pre-group between completers, mid-completers and non-completers

Pre-group Outcomes		**Means (SD)**			
		Full Completer	**Mid-Completer**	**Non-Completer**	***p***
BPI					
	Pain Intensity	24.59 (6.07)	26.93 (5.61)	23.06 (4.62)	0.187
	Pain Interference	50.44 (10.90)	52.07 (12.02)	45.22 (13.56)	0.161
HADS					
	Anxiety	12.23 (4.37)	13.21 (3.96)	12.70 (3.27)	0.684
	Depression	10.62 (3.79)	12.36 (3.15)	11.72 (2.99)	0.162
MPFI					
	Psych Flexibility	39.72 (11.20)	36.75 (10.57)	37.75 (8.93)	0.616
	Psych Inflexibility	41.30 (9.41)	45.54 (9.84)	39.50 (8.37)	0.205
SCS					
	Self-Compassion	29.85 (8.13)	26.80 (10.10)	28.60 (8.23)	0.418
WEMWBS					
	Mental Wellbeing	19.03 (4.28)	17.50 (5.47)	17.48 (3.67)	0.232

Table 7 Comparison of study variables at pre-group, mid-group and post-group

Outcomes (n=89)		**Means (SD)**					
		Pre-Group	**Mid-Group**	**End-Group**	**F**	***p***	η_p^2
BPI							
	Pain Intensity[SA]	24.66 (6.26)	24.30 (6.75)	24.66 (6.26)	1.277	0.281	0.014
	Pain Interference[GG]	48.87 (12.10)	45.87 (41.02)	42.26 (13.67)	22.088	<0.001	0.201*
HADS							
	Anxiety[HF]	12.32 (4.13)	11.42 (4.34)	10.26 (4.44)	18.876	<0.001	0.177*
	Depression[HF]	10.76 (3.55)	10.20 (3.82)	9.00 (4.20)	18.032	<0.001	0.170*
MPFI							
	Psych Flexibility[HF]	39.21 (10.74)	41.48 (10.61)	43.00 (9.83)	9.391	<0.001	0.096*
	Psych Inflexibility[SA]	41.06 (9.19)	41.06 (9.19)	37.45 (8.70)	20.686	<0.001	0.190*
SCS							
	Self-Compassion[GG]	30.10 (8.04)	30.99 (8.61)	33.39 (9.26)	16.103	<0.001	0.155*
WEMWBS							
	Mental Wellbeing[HF]	18.73 (4.17)	20.13 (4.48)	21.95 (5.04)	35.976	<0.001	0.290**

[SA]Sphericity assumed; [GG]Greenhouse-Geisser correction where ε < 0.75; [HF]Huynh-Feldt correction where ε > 0.75

*small effect size; **moderate effect size based on guidelines by Cohen[62]

Table 8 Post-hoc comparisons of mean differences of study variables between timepoints

Outcomes (n=89)		**Mean Difference T_1 - T_2**			**Mean Difference T_2 - T_3**		
		$\Delta\bar{x}$	***p***	η_p^2	$\Delta\bar{x}$	***p***	η_p^2
BPI							
	Pain Intensity	0.36	0.261	0.014	-0.36	0.261	0.014
	Pain Interference	3.00	0.001	0.112*	3.61	<0.001	0.141*
HADS							
	Anxiety	0.90	0.004	0.091*	1.16	<0.001	0.139*
	Depression	0.56	0.048	0.044	1.20	<0.001	0.192*
MPFI							
	Psych Flexibility	2.27	0.007	0.080	1.51	0.076	0.035
	Psych Inflexibility	0.00	–	–	3.61	<0.001	0.190*
SCS							
	Self-Compassion	0.89	0.033	0.051	2.40	<0.001	0.146*
WEMWBS							
	Mental Wellbeing	1.40	<0.001	0.142*	1.82	<0.001	0.257**

*small effect size; **moderate effect size based on guidelines by Cohen[62]

Post-hoc analyses compared the changes in outcome between the first and second half of the group (Table 8). The analysis showed that the largest improvements occurred in the second half of the group (T_2 - T_3) across all outcome measures, with the exception of pain intensity and psychological flexibility. Psychological flexibility was the only measure to show a lesser effect size in the second half of the group. Interestingly, there was no noticeable difference between means of psychological inflexibility from pre-group to mid-group. Mental wellbeing demonstrated a large effect size in both halves of the PMP. Self-compassion was the outcome with the largest difference in effect size between the first and second halves of the group.

3.1. Mediation Analyses

Mediation analyses were performed to explore the hypothesis that changes in psychological flexibility, psychological inflexibility and self-compassion (the predictor variables) mediate the difference in pain interference, anxiety, depression and mental wellbeing (the dependent variables) from pre-group to post-group. According to Judd et al.'s[61] recommendations, an effect of mediation is indicated under the following conditions: 1) the predictor and dependent variables both significantly change between timepoints (i.e. between T_1 and T_3, as previously confirmed in Tables 7 and 8); 2) the predictor variable predicts the dependent variable at each timepoint (at T_1 and T_3); and 3) the difference of the predictor variable (T_1-T_3) predicts the difference of the dependent variable. An effect of moderation, however, is indicated if the sum of the predictor variable (T_1+T_3) predicts the difference of the dependent variable. This last analysis was included to ensure that the effect is one of mediation, not moderation.

As seen in Table 9, self-compassion predicted pain interference at pre-group (β = 0.305, p = 0.013) and post-group (β = 0.321, p = 0.004). The mean difference in self-compassion significantly predicted the mean difference in pain interference (β = 0.263, p = 0.014). This shows mediation of the treatment effect on pain interference by self-compassion. The mean sum of self-compassion did not significantly predict the mean differences in pain interference, which shows that self-compassion is not a moderator on the difference in pain interference from pre-group to post-group. Psychological

inflexibility was found to predict pain interference at pre-group (β = 0.266, p = 0.017), but not at post-group (β = 0.204, p = 0.054), and was therefore not a mediator of the treatment effect on pain interference from pre-group to post-group.

Psychological inflexibility predicted anxiety at pre-group (β = 0.461, p < 0.001) at post-group (β = 0.427, p < 0.001) (Table 10). The mean difference in psychological inflexibility, however, did not predict the mean difference in anxiety (β = 0.157, p = 0.131). This shows no mediation of the treatment effect on anxiety by psychological inflexibility. Results were non-significant for the other predictor variables at both timepoints, except for self-compassion, which was shown to predict post-group anxiety (β = 0.282, p = 0.003). None of the predictor variables were found to mediate or moderate the difference in anxiety from pre-group to post-group.

Psychological flexibility, psychological inflexibility and self-compassion predicted depression at pre-group (β = 0.290, p = 0.008; β = 0.271, p = 0.005; β = 0.225, p = 0.031) and post-group (β = 0.238, p = 0.015; β = 0.235, p = 0.016; β = 0.251, p = 0.013) (Table 11). Only the mean difference in psychological flexibility and psychological inflexibility significantly predicted the mean difference in depression (β = 0.249, p = 0.013; β = 0.346, p = 0.001). This shows mediation of the treatment effect on depression by psychological flexibility and inflexibility, but not self-compassion (β = 0.144, p = 0.124). The mean sums of psychological flexibility and psychological inflexibility did not significantly predict the mean difference in depression, which shows that psychological flexibility and psychological inflexibility are not moderators on the difference in depression from pre-group to post-group.

Psychological flexibility and inflexibility predicted mental wellbeing at pre-group (β = 0.412, p < 0.001; β = 0.240, p = 0.005) and post-group (β = 0.482, p < 0.001; β = 0.192, p = 0.024) (Table 12). The mean difference in both psychological flexibility and psychological inflexibility significantly predicted the mean difference in depression (β = 0.421, p < 0.001; β = 0.306, p = 0.001). This shows mediation of the treatment effect on mental wellbeing by psychological flexibility and psychological inflexibility. The mean sum of psychological flexibility and psychological inflexibility did not significantly predict the

mean difference in mental wellbeing, which shows that psychological flexibility and psychological inflexibility are not moderators on the difference in mental wellbeing from pre-group to post-group. Self-compassion was found to predict mental wellbeing at pre-group (β = 0.228, *p* = 0.015), but not at post-group (β = 0.161, *p* = 0.066), and was therefore not a mediator of the treatment effect on mental wellbeing from pre-group to post-group.

4. Discussion

The results of this study demonstrated that a CFT PMP significantly improved measures of distress and disability related to chronic pain in adults. After 11 weeks, there was improvement across scores of pain interference, anxiety, depression, psychological flexibility, psychological inflexibility, self-compassion and mental wellbeing. These improvements are demonstrative of small effect sizes, with the exception of mental wellbeing, which improved with moderate effect size (according to guidelines by Cohen[63]). There was no significant difference in scores of pain intensity, which is not surprising as PMPs do not seek to target pain intensity as a primary objective. These results are in line with current early research on the benefits of compassion interventions for chronic pain[39–41]. Unfortunately, no follow-up was conducted during this study; one other study in this area reported maintained gains at 3 months[41].

The second finding of this study was that the biggest change occurred in the second half of the PMP (although statistically significant improvements were found even at mid-point). This was true of all measured domains, excluding psychological flexibility and psychological inflexibility. Psychological flexibility was the only measure to show a lesser effect size in the second half of the group and, interestingly, there was no noticeable difference between means of psychological inflexibility from pre-group to mid-group. Perhaps this is not a surprising result in the context of a CFT intervention, where there is no explicit reference to psychological flexibility or inflexibility. These larger effect sizes in the second half of the PMP is of clinical significance in the NHS, where there is increasing pressure on services to maximise limited resources and provide shorter interventions.

Table 9 Mediation analyses for psychological flexibility (MPFI), psychological inflexibility (MPFI) and self-compassion (SCS) on pain interference

					Standardised β Coefficients			
Dependent Variable	**Predictor**	**R^2**	**F**	***p***	**β**	**t**	***p* (β)**	**95% CI**
T_1 Pain Interference	T_1 Psychological Flexibility	0.190	6.802	<0.001	-0.070	-0.567	0.572	-0.335, 0.187
	T_1 Psychological Inflexibility				0.266	2.424	0.017	0.060, 0.602
	T_1 Self-Compassion				0.305	2.548	0.013	0.095, 0.771
T_3 Pain Interference	T_3 Psychological Flexibility	0.266	14.005	<0.001	0.062	0.588	0.558	-0.195, 0.359
	T_3 Psychological Inflexibility				0.204	1.945	0.054	-0.006, 0.602
	T_3 Self-Compassion				0.321	2.949	0.004	0.155, 0.786
T_1-T_3 Pain Interference	T_1-T_3 Psychological Flexibility	0.123	4.062	0.009	0.135	1.120	0.230	-0.100, 0.413
	T_1-T_3 Psychological Inflexibility				0.057	0.516	0.607	-0.226, 0.385
	T_1-T_3 Self-Compassion				0.263	2.502	0.014	0.083, 0.726
$T_{1+}T_3$ Pain Interference	$T_{1+}T_3$ Psychological Flexibility	0.016	0.457	0.713	-0.098	-0.684	0.496	-0.214, 0.105
	$T_{1+}T_3$ Psychological Inflexibility				-0.019	-0.148	0.883	-0.714, 0.150
	$T_{1+}T_3$ Self-Compassion				-0.023	-0.158	0.875	-0.205, 0.175

Table 10 Mediation analyses for psychological flexibility (MPFI), psychological inflexibility (MPFI) and self-compassion (SCS) on anxiety

					Standardised β Coefficients			
Dependent Variable	**Predictor**	**R^2**	**F**	***p***	**β**	**t**	***p* (β)**	**95% CI**
T_1 Anxiety	T_1 Psychological Flexibility	0.612	17.530	<0.001	0.116	1.028	0.293	-0.039, 0.128
	T_1 Psychological Inflexibility				0.461	4.771	<0.001	0.123, 0.298
	T_1 Self-Compassion				0.151	1.431	0.156	-0.031, 0.188
T_3 Anxiety	T_3 Psychological Flexibility	0.473	34.732	<0.001	0.074	0.833	0.407	-0.047, 0.114
	T_3 Psychological Inflexibility				0.427	4.797	<0.001	0.125, 0.301
	T_3 Self-Compassion				0.282	3.058	0.003	0.050, 0.233
T_1-T_3 Anxiety	T_1-T_3 Psychological Flexibility	0.466	8.142	<0.001	0.319	3.038	0.003	0.045, 0.217
	T_1-T_3 Psychological Inflexibility				0.157	1.522	0.131	-0.024, 0.179
	T_1-T_3 Self-Compassion				0.137	1.385	0.169	-0.032, 0.182
$T_{1+}T_3$ Anxiety	$T_{1+}T_3$ Psychological Flexibility	0.094	0.261	0.853	-0.004	-0.031	0.976	-0.056, 0.055
	$T_{1+}T_3$ Psychological Inflexibility				-0.063	-0.485	0.629	-0.071, 0.043
	$T_{1+}T_3$ Self-Compassion				-0.041	-0.281	0.779	-0.077, 0.058

Table 11 Mediation analyses for psychological flexibility (MPFI), psychological inflexibility (MPFI) and self-compassion (SCS) on depression

					Standardised β Coefficients			
Dependent Variable	**Predictor**	**R^2**	**F**	***p***	**β**	**t**	***p* (β)**	**95% CI**
T_1 Depression	T_1 Psychological Flexibility	0.637	19.994	<0.001	0.290	2.716	0.008	0.026, 0.169
	T_1 Psychological Inflexibility				0.271	2.873	0.005	0.033, 0.183
	T_1 Self-Compassion				0.225	2.189	0.031	0.009, 0.196
T_3 Depression	T_3 Psychological Flexibility	0.618	23.910	<0.001	0.238	2.460	0.015	0.019, 0.172
	T_3 Psychological Inflexibility				0.235	2.443	0.016	0.020, 0.188
	T_3 Self-Compassion				0.251	2.514	0.013	0.024, 0.199
T_1-T_3 Depression	T_1-T_3 Psychological Flexibility	0.557	13.180	<0.001	0.249	2.523	0.013	0.020, 0.164
	T_1-T_3 Psychological Inflexibility				0.346	3.573	0.001	0.068, 0.240
	T_1-T_3 Self-Compassion				0.144	1.554	0.124	-0.020, 0.161
$T_{1+}T_3$ Depression	$T_{1+}T_3$ Psychological Flexibility	0.004	0.112	0.953	-0.013	-0.088	0.930	-0.052, 0.048
	$T_{1+}T_3$ Psychological Inflexibility				-0.056	-0.429	0.669	-0.063, 0.041
	$T_{1+}T_3$ Self-Compassion				0.072	0.494	0.622	-0.046, 0.076

Table 12 Mediation analyses for psychological flexibility (MPFI), psychological inflexibility (MPFI) and self-compassion (SCS) on mental wellbeing

					Standardised β Coefficients			
Dependent Variable	**Predictor**	**R^2**	**F**	***p***	**β**	**t**	***p* (β)**	**95% CI**
T_1 Mental Wellbeing	T_1 Psychological Flexibility	0.724	32.322	<0.001	0.412	4.315	<0.001	0.090, 0.243
	T_1 Psychological Inflexibility				0.240	2.848	0.005	0.035, 0.196
	T_1 Self-Compassion				0.228	2.480	0.015	0.025, 0.225
T_3 Mental Wellbeing	T_3 Psychological Flexibility	0.532	43.890	<0.001	0.482	5.722	<0.001	0.169, 0.347
	T_3 Psychological Inflexibility				0.192	2.287	0.024	0.015, 0.211
	T_3 Self-Compassion				0.161	1.856	0.066	-0.006, 0.197
T_1-T_3 Mental Wellbeing	T_1-T_3 Psychological Flexibility	0.405	19.978	<0.001	0.421	4.607	<0.001	0.110, 0.278
	T_1-T_3 Psychological Inflexibility				0.306	3.401	0.001	0.071, 0.269
	T_1-T_3 Self-Compassion				0.077	0.892	0.375	-0.058, 0.152
$T_{1+}T_3$ Mental Wellbeing	$T_{1+}T_3$ Psychological Flexibility	0.012	0.370	0.774	-0.091	-0.628	0.532	-0.082, 0.042
	$T_{1+}T_3$ Psychological Inflexibility				0.021	0.162	0.872	-0.059, 0.069
	$T_{1+}T_3$ Self-Compassion				-0.042	-0.292	0.771	-0.086, 0.064

Since self-compassion is positively correlated with psychological flexibility, and negatively correlated with psychological inflexibility[38], it would be expected that these two measures would change along with self-compassion. The slowness of the change may be reflected in the fact that they were not the primary targets. The initial improvement in psychological flexibility in the first half of the group may be attributable to novel processes, as opposed to the bigger change in self-compassion that occurs during the second half of the group, perhaps indicative of skill acquisition. Group cohesion has also been shown to predict outcome, and six weeks is considered adequate time for these dynamics to develop[64].

Hayes[65] comments on the idea that change is not always linear, for example, patterns of change in psychotherapies may involve rapid response to treatment, sudden gains in between individual sessions and irregular spikes throughout the intervention. This study did not collect outcome measures weekly to be able to comment on a specific pattern, but there is evidence here of a nonlinear pattern of change, possibly reflective of destabilising and reorganising processes in therapy[65].

The third finding of this study demonstrated self-compassion to be a superior mediator of the treatment effect on pain interference, compared to psychological flexibility and psychological inflexibility. Both psychological flexibility and inflexibility, however, were found to be better mediators of improvements in depression and mental wellbeing, compared to self-compassion. Psychological flexibility, psychological inflexibility and self-compassion were not found to mediate improvements in anxiety. It is interesting to note that self-compassion mediated the only pain-specific construct being measured in this study (pain interference), which suggests that there may be a specific benefit in targeting self-compassion within pain interventions.

These findings partly fit in line with previous research, although appear contradictory in the context of studies that have not measured self-compassion, psychological flexibility and psychological inflexibility together. For example, in one study, low self-compassion was highlighted as a significant predictor of pain disability[37], whilst in another, psychological inflexibility was demonstrated to be a mediator on

pain disability[66]. The findings of the current research assert that self-compassion has more dominant influence over improvements in pain disability and interference, when compared in the same model. It has already been established that feelings of shame and guilt are common in living with chronic pain[6,8], and it may be the case that targeting these complex, internalised barriers is an efficacious way to manage the negative impact of chronic pain.

According to Vowles[67], psychological flexibility mediated improvements in anxiety and depression, however, pain acceptance and self-compassion were the strongest overall mediators when all mediators were tested in the same model. It was surprising that, in the current study, psychological flexibility and inflexibility were found to mediate improvements in depression and wellbeing when the current intervention did not have an explicit focus on the concept. This may be explained by measurement discrepancies in using different scales (e.g. depression was measured using the British Columbia Major Depression Inventory in Vowles' study, and in the current study, the HADS was used). Studies that report a mediating effect of psychological flexibility, psychological inflexibility or self-compassion on depression also reported similarly for anxiety[38,68], which the current findings did not support. It may be the case that process variables for improvements in anxiety were attributable to common group processes, such therapeutic solidarity, modelling and belonging, or other concepts that were not measured in this study (e.g. pain acceptance, thinking styles or control over pain).

Discrepancies between the current research's findings and existing literature can be also be a reflection of the overlap between the three constructs. Self-compassion has been demonstrated to be the most robust mediator in trial of ACT for chronic pain[67], even when not explicitly addressed in the intervention. In a study where ACT was used as an intervention to promote self-compassion and reduce psychopathology, psychological flexibility was established as a significant mediator of changes in self-compassion[69]. Others have suggested that ACT, like CFT, can be used to address criticism, stigma and shame[70], even though this a key element of CFT. The literature is clearly reflecting the conceptual overlaps between ACT and CFT. Luoma and Platt[70] suggest that although self-compassion is implied in ACT, those high in self-criticism and shame will require a more directive approach, for example,

explicitly integrating values work to include the relationship with the self. The evidence base would suggest that these two approaches can be seamlessly integrated in order to maximise outcomes.

4.1. Strength and Limitations

The clinical setting of the intervention is both a strength and a limitation. Comments here are similar to those noted by Penlington[39], whose research was completed within a similar context. On one hand, realistic participant recruitment strengthens external validity; the PMP accepted those with co-morbidities and no PMP attendees were excluded from the research. This means that the results can be better generalised to a wider chronic pain population. On the other hand, internal validity was compromised as it was likely that individuals used other personal methods of pain management alongside the intervention. As such, it was not possible to deduce whether the gains were solely based on completion of the PMP. It was also not possible to estimate the other benefits of participating in a group, for example, therapeutic comradery in a supportive, clinical environment. The standardised betas of the mediators demonstrated only modest effect sizes, and so, it is entirely plausible that there are other factors influencing participant improvement, such as regular exercise, anticipatory hope and patient expectation[15], therapeutic alliance, therapist effects[71] and generic group benefits, such as therapeutic solidarity and group cohesion. Demand characteristics are also likely to serve as an extraneous variable.

The attrition rate in this study was 26.2%. This is consistent with the literature in this area, although attrition rates for PMPs vary, ranging from 9–42%[72]. Attrition has been associated with higher levels of pain, disability and depression[73], employment and disability benefits, literacy difficulties, pain catastrophising, history of substance abuse and trauma[74], poor self-efficacy and physical function[75]. In order to reduce attrition, Richmond et al.[76] recommends the management of unrealistic expectations, as well as stressing the importance of self-management and family support. This study did not uncover any differences between the pre-group outcome measures (pain, anxiety, depression, psychological flexibility, psychological inflexibility, self-compassion and mental wellbeing) of completers, mid-

completers and non-completers, nor between pre-group outcomes and basic demographics. Group sizes for the latter analysis were small, which will increase the likelihood of type II errors.

The use of LOCF is not without bias. This technique is deemed to be a conservative way of handling missing data[77], but it makes the assumption that the intervention will not cause deterioration below pre-group measurements, which may cause an overestimation of the treatment effect. Listwise deletion was used on roughly a quarter of the total data (where missing data was greater than 10%). This may also increase the likelihood of type II errors, although, this is not considered to be a problematic method if missing data is random and the sample size is large enough to remain adequately powered[59,78], as was calculated a priori.

Judd, Kenny and McClelland's[61] guidelines for within-subject mediation follows a component approach instead of index approach of mediation. The component approach requires joint-significance testing of multiple parameter estimates, and therefore, reduces the likelihood of falsely identifying mediation of the treatment effect on *one* dependent variable by a predictor. Overall, however, the large number of analyses are likely to inflate the risk of type I errors.

There was some (albeit limited) regulation around fidelity to treatment in this study. Where possible, facilitators attended CFT training. No specific manual exists for CFT adapted for chronic pain, but facilitators produced and followed the same week-by-week structure for every group (Appendix 9). There was regular supervision for Psychologists (individual and group) from qualified Clinical Psychologists in the service. Fidelity to treatment is an area that is poorly documented in psychotherapy research. A review by Perepletchikova et al.[79] compiled data on randomised controlled trials of psychotherapies to investigate which studies systematically addressed treatment fidelity. The authors found that only 3.50% of the studies adequately addressed fidelity to treatment, which included domains such as treatment adherence, therapist competence and supervision.

A strength of this study was its longitudinal design and the inclusion of a baseline at assessment (T_0), prior to the start of the PMP, providing an element of within-subject control. The results of the study

showed no significant change in scores of pain intensity, pain interference, anxiety or depression before beginning the intervention. This cannot be considered a complete control period because only a smaller subset of the questionnaires was collected at assessment (BPI and HADS). This was done because these questionnaires are routinely posted out to participants prior to their one-to-one assessment with a member of the clinical team. It was not decided at this point whether or not a participant was going to be suitable for a PMP, and the extra questionnaires were not added in order to reduce participant burden. There was also a varying number of weeks from the date of assessment to the pre-group introductory group, and so, further assessment data could not be collected at the same time. Nevertheless, inclusion of baseline assessment data suggests that waiting to start a PMP does not promote improvement in psychological wellbeing.

4.2. Conclusion

To date, this is the first longitudinal study to explore the mediating effects of self-compassion, psychological flexibility and psychological inflexibility in a CFT group for chronic pain. The results demonstrate the suitability of using CFT as a group intervention for adults with chronic pain. The largest improvements were found to occur in the second half of the group, which has implications for services in the NHS that are under pressure to provide shorter interventions. Self-compassion, psychological flexibility and psychological inflexibility were found to mediate different measures of improvements, adding to the sparse evidence base in this area. As well as supporting the use of CFT for chronic pain, the results of this research suggest that pain interventions already targeting psychological flexibility and psychological inflexibility are likely to be further improved by involving self-compassion.

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List of Appendices

Appendix 1: Submission Guidelines for *The Clinical Journal of Pain*

The Clinical Journal of Pain

Online Submission and Review System

INSTRUCTIONS FOR AUTHORS

The Clinical Journal of Pain publishes original articles in the following forms: *Clinical investigations:* Present results of original clinical research. *Case reports:* Case reports will no longer be accepted for publication in *Clinical Journal of Pain* and thus no submission for case reports will be accepted as of June 13, 2013. *Reviews:* Comprehensive surveys covering a broad area. They consolidate old ideas and may suggest new ones. They must provide a critique of the literature. *Special articles:* On subjects not easily classified above (e.g., articles on history, education, demography, ethics, socioeconomics, etc.). *Letters to the editor:* These may offer criticism of published material, but must be objective, constructive, and educational. A few references, a small table, or relevant illustrations may be used.

Ethical/Legal Considerations: A submitted manuscript must be an original contribution not previously published (except as an abstract or preliminary report), must not be under consideration for publication elsewhere, and, if accepted, must not be published elsewhere in similar form, in any language, without the consent of Lippincott Williams & Wilkins. Each person listed as an author is expected to have participated in the study to a significant extent. Although the editors and referees make every effort to ensure the validity of published manuscripts, the final responsibility rests with the authors, not with the Journal, its editors, or the publisher. All manuscripts must be submitted on-line through the journal's Web site at http://cjp.edmgr.com. See submission instructions under "On-line manuscript submission."

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Conflicts of Interest and Source of Funding: A has received honoraria from Company Z. B is currently receiving a grant (#12345) from Organization Y, and is on the speaker's bureau for Organization X − the CME organizers for Company A. For the remaining authors none were declared.

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Preparation of Manuscript

Cover Letter. With your manuscript, please submit a brief cover letter describing your manuscript and provide the names and e-mail addresses of 3-4 suggested reviewers. These should be people who are knowledgeable of the topic of the manuscript and who will not have a conflict of interest serving as reviewers. The Editors may or may not enlist these suggested reviewers.

Manuscripts that do not adhere to the following instructions will be returned to the corresponding author for technical revision before undergoing peer review.

General format: Submit manuscripts in English as a Word file. Double space all copy, including legends, footnotes, tables, and references.

Title page: Include on the title page (a) complete manuscript title; (b) authors' full names, highest academic degrees, and affiliations; (c) name and address for correspondence, including fax number, telephone number, and e-mail address; (d) address for reprints if different from that of corresponding author; and (e) sources of support that require acknowledgment.

The title page must also include disclosure of funding received for this work from any of the following organizations: National Institutes of Health (NIH); Wellcome Trust; Howard Hughes Medical Institute (HHMI); and other(s).

Structured abstract and key words: Limit the abstract to 250 words. Do not cite references in the abstract. Limit the use of abbreviations and acronyms. Use the following subheads: Objectives, Methods, Results, and Discussion. List three to five key words.

Text: Organize the manuscript into four main headings: Introduction, Materials and Methods, Results, and Discussion. Define abbreviations at first mention in text and in each table and figure. If a brand name is cited, supply the manufacturer's name and address (city and state/country). Acknowledge all forms of support, including pharmaceutical and industry support, in an Acknowledgments paragraph.

The Clinical Journal of Pain does not have a required number of words for the text. Please treat your subject thoroughly but not excessively. Perusing several back issues to familiarize yourself with typical accepted article length is recommended.

Abbreviations: For a list of standard abbreviations, consult the *Council of Biology Editors Style Guide* (available from the Council of Science Editors, 9650 Rockville Pike, Bethesda, MD 20814) or other standard sources. Write out the full term for each abbreviation at its first use unless it is a standard unit of measure.

References: The authors are responsible for the accuracy of the references. References should be cited by number in order of citation in the text. Key the references (double-spaced) at the end of the manuscript, in numbered order. Cite unpublished data, such as papers submitted but not yet accepted for publication or personal communications, in parentheses in the text (H. E. Marman, M.D.,

unpublished data, February, 1997). If there are more than three authors, name only the first three authors and then use et al. Refer to the *List of Journals Indexed in Index Medicus* for abbreviations of journal names, or access the list at http://www.nlm.nih.gov/tsd/serials/lji.html. Citations throughout the article and in all tables and figures should include only the reference number rather than the year of publication.

Appendix 2: Data Extraction Form

General Information

Date form completed	
Authors and Year	
Title	
Abstract	
Background/rationale	
Objectives	

Methods

Study design	
Setting	
Participants	
Variables	
Data sources / measurement	
Bias	
Study size	
Quantitative variables	
Statistical methods	

Results

Participants	
Descriptive data	
Outcome data	
Main results	
Other analyses	

Discussion

Key results	
Limitations	
Strengths	
Interpretation	
Generalisability	

Appendix 3: Quality Criteria Checklists

Quality item	*A study can be awarded a maximum of one star for each numbered item*	*Rating* **/0*	*Comments*
1. Does the study adequately represent FMS in the community?	• Truly representative (random sampling)* • Somewhat representative (non-random sampling)* • Selected group • No description of the derivation of the cohort		
2. Type of data	• Prospective* • Retrospective	*(N/A for cross-sectional)*	
3. Sample size	• Adequate to detect effect* (based on Cohen, 1992) • Not adequate to detect effect		
4. Selection of the non-FMS cohort?	• Drawn from the same community as the FMS cohort* • Drawn from a difference source • No description of the derivation of the non-FMS cohort		
5. Definition of non-FMS cohort	• No history of FMS* • No description		
6. Comparability of cohorts on the basis of the design or analysis	• The study controls for relevant confounders (e.g. age, sex, etc)* • The study does not control for relevant confounders		
7. Ascertainment of FMS	• Specialist medical record (e.g. rheumatologist)* • Structured interview (including review by medic)* • Validated measurement tool* • Non-validated measurement tool • Written self-report		

	• No description		
7.1 Demonstration that FMS was not present at start of study	• Yes* • No	*(cohort only)*	
8. Assessment of outcome	• Independent blind assessment* • Record linkage* • Self-report • No description		
9. Response rate / follow-up	• Complete follow-up – all subjects accounted for* • Satisfactory follow-up and satisfactory attrition rate ⩾50%* • Unsatisfactory follow-up an unsatisfactory attrition rate • No statement		
9.1 Was follow-up long enough for outcomes to occur?	• Yes (2+ years)* • No (<2 years)	*(cohort only)*	
10. Statistical test	• The statistical test used to analyse the data is clearly described and appropriate, and the measurement of the association is presented* • The statistical test is not appropriate, not described or incomplete		
	Overall score		

Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

09 February 2018

Dear Miss Tin,

Study title:	**How do self-compassion and psychological flexibility mediate change in a Compassion-Focused Therapy group for chronic pain?**
REC reference:	**17/EM/0465**
Protocol number:	**CAHSS1710/07**
Amendment number:	**26.01.2018**
Amendment date:	**26 January 2018**
IRAS project ID:	**234604**

The above amendment was reviewed on 09 February 2018 by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

There were no ethical issues

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP) [Notice of Substantial Amendment.pdf]	26.01.2018	26 January 2018
Other [Amended Questionnaire Pack MERGED.pdf]		
Participant consent form [Amended Consent Form R1 ST 25 January 2018.docx]	2	25 January 2018
Participant information sheet (PIS) [Amended PIS R1 ST 25	2	25 January 2018

January 2018.docx]		
Research protocol or project proposal [Amended Protocol R1 ST 25 January 2018.docx]	2	25 January 2018

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

17/EM/0465: Please quote this number on all correspondence

Yours sincerely,

Mr Murthy Nyasavajjala

Chair

E-mail: NRESCommittee.EastMidlands-Nottingham1@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Miss Melissa Taylor, NHS Lothian Research and Development Office*

Appendix 5: Study Protocol

Study Protocol

Title of Research

How do self-compassion and psychological flexibility mediate change in a Compassion-Focused Therapy group for people with chronic pain?

Protocol Author

Su Tin, Trainee Clinical Psychologist

List of Abbreviations

ACT Acceptance and Commitment Therapy
CBT Cognitive-Behaviour Therapy
CFT Compassion-Focused Therapy

Background: The Impact of Chronic Pain

Chronic pain is pain that lasts longer than 3 months and affects 18% of the Scottish population (NHS QIS, 2008). Unlike acute pain, it is not an indication of sinister disease processes. In the process of learning to live with chronic pain, people may have experiences of being disbelieved by family, friends and health professionals, struggle with beliefs of being a burden on their loved ones and feel disappointment at not being able to fulfil previously held roles in the family (Smith & Osborn, 2007). Chronic pain becomes a stigma and these experiences, in conjunction with debilitating physical symptoms, can have a profound impact on mood, behaviour and general wellbeing. It is not the intensity of the pain that affects quality of life; the issue is more relational, for example, the negative beliefs that someone may hold about their pain (Lamé et al., 2005). Negative cognitions and emotions are activated by pain-related difficulties and multi-disciplinary treatments for chronic pain target the management of these internal experiences and daily functioning, rather than attempting to eliminate the physical sensation of pain.

Current Treatment Models in Chronic Pain

Alongside education and physical exercise, Cognitive Behaviour Therapy (CBT) and Acceptance and Commitment Therapy (ACT) are used across multidisciplinary pain management programmes in the treatment of chronic pain. CBT is recommended by the Scottish Intercollegiate Guidelines Network (SIGN) Guideline 136 and ACT is recommended by the American Psychological Association (APA Division 12: Society of Clinical Psychology).

CBT aims to identify, examine and alter the impact of distressing, unhelpful cycles of cognition and behaviour. Techniques such as graded activation and graded exposure are also used to help achieve sustainable levels of activity and reduce avoidance (Williams et al., 2012; Bailey et al., 2010). Mediator analyses have identified self-efficacy as the mechanism of change in CBT for chronic pain (Turner et al., 2007), which is a construct targeted by many other psychotherapies, not only CBT. Acceptance and Commitment Therapy (ACT) aims to develop mindfulness, willingness to experience undesirable

internal experiences and foster distance between the self and negative thoughts. The overall process underlying the methods used in ACT can be conceptualised as 'psychological flexibility' (Hayes et al., 1999). A review by Hughes and others (2017) examined 11 trials, finding significant medium to large effect sizes for measures of acceptance and psychological flexibility.

Comparisons between individuals on an ACT and a CBT pain management programme has not uncovered significant differences across improvements sustained in pain interference, depression, anxiety, and quality of life (Wetherall et al., 2011). Gaudinano (2009) notes that more attention should be focused on the mechanisms of action as opposed to pitting separate treatments against each other and drawing conclusions about their efficacy based on differences across outcomes. Many psychotherapies share constructs and are often shown to result in similar outcomes.

Psychological Flexibility

Cross-sectional studies do not give explanation into the direction of the relationship between process and outcome variables; it is difficult to deduce if outcomes have improved because psychological flexibility has increased, or if psychological flexibility has increased because the outcomes have improved. A number of cross-sectional studies have, however, proven that psychological inflexibility is linked to anxiety, depression and wellbeing (e.g. Masuda & Tully, 2011). Vowles and others (2014) performed correlation and regression analyses and reported significant relationships between psychological flexibility and measures of disability, emotional functioning, pain acceptance and valued activity. Four key process variables of psychological flexibility were investigated by McCracken and Gutierrez-Martinez (2011): pain acceptance, values-based action, psychological acceptance and mindfulness. General acceptance was found to show the largest effect size, predicting gains in outcome more so than those accounted for by pain acceptance. The authors note that the concept itself is a tricky idea to capture accurately, because behaviour related to psychological flexibility cannot be measured until one has a concept of psychological flexibility, which affects measurement of the baseline.

Self-Compassion

Compassion-focused therapy (CFT) was developed for individuals who struggle with shame and self-criticism (Gilbert, 2009), both of which can be conceptualised as examples of distressing private experiences in the ACT model. It aims to promote a compassionate internal relationship with the self, drawing on the ability to view distressing experiences with kindness, understanding and shared humanity (Neff, 2003). Shame involves a negative evaluation of the *self*, unlike guilt, which involves a negative evaluation of *behaviour* (Lutwak et al., 2003). These complex emotions and cognitions are relevant in the context of chronic pain because of the experience in losing and adjusting to an identity. Purdie and Morley (2016) note that chronic pain is frequently invalidated by society and this constant negative social evaluation can result in a shameful appraisal of a person's sense of self. In this sense, CFT targets self-acceptance in the same way as ACT, but from a different perspective by bringing social inclusion into awareness.

The positive influence of self-compassion is beginning to be investigated across a range of long-term health conditions, such as diabetes (Friis et al., 2015) and cancer (Pinto-Gouveia et al., 2014). To date, however, there is little research on self-compassion and chronic pain. Wren and others (2012) found that self-compassion was a significant predictor of mood, negative pain beliefs and disability related to pain. This cross-sectional study indicated that self-compassion may be significant in predicting pain adjustment, but can only comment on association and not causal relationships. The authors suggest that future research in this area could examine interventions specifically designed to promote self-

compassion. Marshall and Brockman (2016) reported self-compassion to significantly correlate with processes of psychological flexibility, and self-compassion actually predicted mental wellbeing over and above psychological flexibility. This indicates that combining these therapies may result in improved treatment outcomes. This study was, however, conducted on a non-clinical population which may limit generalisability. Empirical research examining links between these two constructs is limited.

Rationale

There is a need for evidence-based answers to explain why and how psychological interventions are successful (Kazdin, 2007). Multimodal treatments are becoming the norm and breaking down these components to examine individual efficacies is not a good use of resources (Wicksell et al., 2010). CFT offers a complementary approach to be used alongside current interventions, targeting the inevitable feelings of shame and self-criticism in the process of adjusting to chronic pain. A strong correlation between self-compassion and psychological flexibility has already been established, and gaining insight into the direction of the relationship between these concepts and treatment outcome would be the next logical step. By focusing on mechanisms of change, better theories can be developed and may promote treatment efficacy (e.g. by matching to patient need). This would be a far more efficient way to develop interventions, whilst maintaining a person-centred delivery of care.

Principal Research Question

- Do self-compassion and psychological flexibility mediate change in a Compassion-Focused Therapy group for adults with chronic pain?

Secondary Research Questions

- Which is the better predictor of change - self-compassion or psychological flexibility?

Methodology

Participants

Participants will be adults with chronic pain who attend and complete the CFT-incorporated groups at the Lothian Chronic Pain Service / Pain Management Programme.

Inclusion Criteria

- Chronic Pain lasting a minimum of 3 months
- Fluency of English sufficient for participation in the group and completion of questionnaires
- Aged 18+ (no upper age limit)
- Ability to provide informed consent as judged by the clinical team

Exclusion Criteria

- Active substance misuse
- Active suicidality
- Terminal illness
- Inability to provide informed consent (as defined by the Five Statutory Principles of the Mental Capacity Act, Code of Practice, 2007)

Design

This study will follow a within-group (non-randomised) effectiveness-implementation design (Curran, 2012). Five self-report measures will be completed by participants at three specified time periods (pre-, mid- and post-group; see *Procedure* below).

Recruitment

2-3 new Pain Management Programme groups start every month, each running for 11 weeks at the Astley Ainslie Hospital in Edinburgh. 6 groups run every week and each group is booked for a maximum of 15 people. These groups are run by at least two qualified members of the clinical team (Clinical Psychologists and Physiotherapists). There will be no need to advertise the research outwith normal clinical operations because clinical staff will offer all group participants the opportunity to participate in the research during their initial assessment, and data collection will overlap with existing routine outcome measures.

Procedure

Potential participants will be identified through their initial assessment upon referral to the Chronic Pain Service. Those who are deemed to be suitable for a Pain Management Programme (e.g. capacity, motivation) will be offered an introductory group session, followed by invitation to an upcoming 11-week group. Information sheets and consent forms will be given out at the start of the group (week 1), to be completed and returned the following week. The information sheets will contain details about the purpose of the research, expectations of the participant in taking part and further information about consent, potential benefits, confidentiality and details of the researchers. Participants will be given time to consider the information and direct questions to the clinical team, to go home and consider the information privately, and also given the opportunity to phone the service and ask further questions if desired. Those who can provide written informed consent will complete pre-group measures at the start of week 1. Mid-group measures will be completed at the end of week 5 and post-group measures will be completed at the end of week 11. (See section 6.4 for details of outcome measures.) The clinical team will be available if participants require support to complete the measures (e.g. literacy issues). The data for participants who do not complete the group will not be used in the final analysis.

Intervention

All groups will follow the same 11-week, structured timetable, using Compassion-Focused Therapy. As there are no current guidelines for using CFT in chronic pain, exercises have been adapted from 'Compassion Focused Therapy for Dummies' (Welford, 2016), incorporating the key elements of CFT (Gilbert, 2009).

Data Collection

Demographic information routinely collected by the service will be used for descriptive statistics (gender, age, area of residence, pain diagnoses and other relevant physical health conditions, duration of pain, employment status and recent pain-related contact with healthcare services). The following self-report measures will be completed by participants at the beginning of week 1 (start) and at the end of week 11 (end). Questionnaires denoted with '*' will be completed by participants at these time intervals and, additionally, at week 5 (mid-point).

Anxiety and Depression*

The Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) is a 14-item measure of the symptoms of anxiety (7 items) and depression (7 items) in individuals with physical health issues.

Each of the items are scored from 0 to 3, where a higher score depicts greater frequency or intensity of the described symptom over the last week (e.g. "I get sudden feelings of panic" and "I have lost interest in my appearance"). Anxiety and depression are rated separately, each allowing for a minimum score of 0 or a maximum score of 21. Bjelland et al. (2002) reviewed 747 papers using the HADS and demonstrated a two-factor structure (i.e. anxiety and depression), with a high level of internal consistency for both the anxiety (Cronbach's α = .83) and depression (Cronbach's α = .82) subscales. Michopoulos et al. (2008) reported a high test-retest reliability of .94 over a 20-day period.

Mental Wellbeing*

The shortened version of the Warwick-Edinburgh Mental Wellbeing Scale (Taggart et al., 2015) (SWEMWBS; Stewart-Brown et al., 2009) is a 7-item measure reporting on subjective positive mental wellbeing and psychological functioning over the last two weeks. It aims to cover a broad range of positive mental health concepts (e.g. "I've been feeling confident" and "I've been feeling close to other people") but does not include spirituality or socioeconomic factors. Each of the items on the measure require a response on a Likert scale, from 1 (none of the time) to 5 (all of the time). This yields a minimum score of 7 and a maximum score of 35 (higher score indicating greater well-being). The SWEMWBS has a test-retest reliability of .83 and demonstrates stability after one week (Stewart-Brown et al., 2009).

Pain

The Brief Pain Inventory (short form, BPI-SF; Cleeland & Ryan, 1994) is a 9-item measure designed to capture two aspects of pain: pain interference (with daily living) and pain severity. These two distinct dimensions have been confirmed through factor analysis. Responses to items on this measure range from 0 (does not interfere) to 10 (completely interferes) on the pain interference subscale and 0 (no pain) to 10 (pain as bad as you can imagine) on the pain severity subscale. The BPI-SF demonstrates stable test-retest reliability and high internal consistency, with Cronbach's α ranging from .80 to .92 (Cleeland, 2009). The Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials (IMMPACT; Dworkin et al., 2005) recommends that all chronic pain research should include outcomes in pain interference and pain severity.

Self-Compassion*

Self-Compassion Scale (short form, SCS-SF; Neff, 2003) is a 12-item measure designed to assess a person's kindness and understanding towards themselves during difficult times. The three elements of self-compassion as defined by Neff (2003) exist on a dichotomy: self-kindness vs. self-judgement; common humanity vs. isolation; and mindfulness vs. over-identification. Responses to these items are indicated on a Likert scale, ranging from 1 (almost never) to 5 (almost always). The SCS-SF has a strong correlation with the long form measure, and factor analysis has validated the six-factor model, in addition to the single higher-order factor of self-compassion (Raes et al., 2011). The SCS-SF shows high internal consistency (Cronbach's α = .86; Raes et al., 2011) and good test-retest reliability over three weeks (scores of at least .8 across all subscales; Neff, 2003).

Psychological Flexibility*

Multi-Dimensional Psychological Flexibility Inventory (short form, MPFI-SF; Rolffs et al., 2016) is a 24-item measure assessing the flexibility of a person's response to negative internal experiences (e.g. thoughts and feelings). Psychological flexibility allows a person to carry these negative experiences whilst living their life in a meaningful, values-directed way. Twelve dimensions have been validated in the 6-factor model of psychological flexibility (Rolffs et al., 2016), the Hexaflex model (Hayes et al., 2011). Psychological flexibility encompasses present moment awareness, values, committed action,

self-as-context, defusion and acceptance. Psychological inflexibility encompasses lack of contact with the present moment, lack of contact with values, inaction, self-as-content, fusion and experiential avoidance. Response to items range from 0 (never true) to 6 (always true) of items in the context of the last two weeks. The MPFI has been shown to have higher levels of internal consistency than other measures of psychological flexibility (Rolffs et al., 2016).

Sample Size

Fritz and MacKinnon (2007) propose guidelines for recommended sample sizes in order to detect mediation effects with .8 power. These guidelines are informed by existing literature in the field. There is less robust research on self-compassion and chronic pain, therefore, this calculation is based on research in psychological flexibility and chronic pain.

McCracken and Gutierrez-Martinez (2011) conducted correlational analyses on the processes of psychological flexibility following a group intervention based on ACT. These processes included acceptance of pain, mindfulness, psychological acceptance and values-based action (r values between 0.33 and 0.55). These positive correlations indicate that the group intervention was related to higher levels of psychological flexibility. A review by Hayes and others (2006) identified several studies that reported correlational effect sizes between acceptance, and depression/anxiety/daily functioning related to chronic pain (r = -0.58/-0.66/0.47 respectively). These negative correlations illustrate that higher levels of psychological flexibility were related to better outcomes. Based on these correlational effect sizes, Fritz and MacKinnon's guidelines suggest that a sample size of 53-71 is required.

Analysis

The analysis will focus on the proposed mediating factors (self-compassion and psychological flexibility) and how they explain the outcome of the CFT-incorporated group intervention. In order to study the processes of change, this study will measure change in mediators and outcomes over the course of the group. In a mediation model, the effect of the independent variable (IV; CFT group) on a dependent variable (DV; outcome/change in symptoms) is conveyed through a third mediating variable. In order to be a mediator, a variable must change during the intervention, be associated with the intervention, and have an impact on the outcome.

In this study, it is hypothesised that self-compassion and/or psychological flexibility are the mediating variables that explain the influence of the group intervention on eventual outcome, i.e. the overall change in symptoms at the end of the group. Linear regression and nonparametric bias-corrected bootstrap, which corrects for skew in the data, will be applied to the data using SPSS, using the PROCESS macro. An effect of mediation will be indicated if the confidence interval does not contain zero. Missing data will be handled using either the maximum likelihood or multiple imputation method, as recommended in literature.

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Version 2 (25/01/18)

Information Sheet for Participants

Pain Management Research Project

You are being invited to take part in a doctoral research project. Before you decide if you would like to take part, we would like you to understand why we are doing this research and what it involves.

Please take time to read the following information carefully and discuss it with others if you like. This information sheet tells you the purpose of the research, what will happen if you agree to take part and how it will be carried out. If there is anything that is not clear, or if you would like more information, please speak to the clinical staff at the Pain Management Service or contact the researcher (contact details at the end of the information sheet). Take your time to decide whether or not you wish to take part.

What is the purpose of the research?

This research aims to study how Compassion-Focused Therapy in a Pain Management Programme might work for people with chronic pain. We know that Pain Management Programmes help patients to manage their pain and improve quality of life, and this research will look into the processes by which this happens. In particular, this research will look at two psychological concepts: 'self-compassion' (kindness to self) and 'psychological flexibility' (willingness to tolerate difficult experiences in order to meet meaningful goals). These concepts help us understand how we think about ourselves in the context of pain.

Why have I been invited to take part?

You have been invited to take part in this research because you have been referred to NHS Lothian's Pain Management Service, and after assessment, you have been offered a place on a Pain Management Programme.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you agree to take part, please complete the consent form and questionnaires given to you at the start of the group (week 1) and bring these along when you return the next

week. If you decide to take part you are still free to withdraw at any time, without giving a reason. Deciding not to take part or withdrawing from the study will not affect the care you receive from the Pain Management Programme.

What will happen if I take part?
You will be given a consent form at the start of the group (week 1). You will be asked to complete five questionnaires at the start (week 1), middle (week 5) and end (week 11) of the group. The questionnaires at the start and end of the group are already routinely used to ensure that we are helping people and that the service is useful. These questionnaires are simple measures of things important to people with chronic pain, such as pain intensity, mood, sense of well-being, and other measures of how we feel about ourselves and how we respond to difficult things in life. The only active difference between participating and not participating in this research is the extra questionnaires you will be asked to complete in the middle of the group.

What are the possible benefits of taking part?
The information we gain will help us to understand how Compassion-Focused Therapy in a Pain Management Programme works. By doing so, we hope that treatments for chronic pain may evolve faster and more efficiently. You may get some satisfaction from being a part of this process.

What are the possible disadvantages and risks of taking part?
Completing the questionnaires at week 5 will take 20-25 minutes. It is unlikely that you will experience any negative effects from taking part in this research. There is a possibility that you may find some of the questionnaires upsetting. If this happens, you are welcome to speak to a member of the clinical team who will be present every week. Alternatively, further support can be accessed through Breathing Space (0800 83 85 87) or The Samaritans (08457 90 90 90).

Will my taking part be kept confidential?
Your data will be analysed by the researcher (Su Tin, Trainee Clinical Psychologist), the Pain Management team and other authorised people to check that the research is being carried out correctly. All are bound by a duty of confidentiality to you as a participant. If you decide to take part in the research, your data will be anonymised so that you cannot be identified from your questionnaires. The data is stored on a secured NHS database and all consent forms and paper questionnaires are kept in a locked drawer in a secure office at the Astley Ainslie Hospital. Personal data will be destroyed after 1 year

and anonymised research data will be reviewed for retention or disposal every 5 years.

What will happen to the results of the research?
The results of this research will be written up as a doctoral thesis submitted to the University of Edinburgh. This will also take the form of an article submitted to a peer-reviewed journal and may be presented at academic conferences. You will not be identified in any report or publication. Please contact us if you would like a copy of the published results.

Who is organising the research and why?
The research is sponsored by the University of Edinburgh and NHS Lothian. It has been organised by the researcher as part of their doctoral thesis.

Who has reviewed the research?
The study proposal has been reviewed by the Ethics Committee at the University of Edinburgh. All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the East Midlands (Nottingham 1) REC. NHS management approval has also been obtained.

Thank you very much for reading this information. If you have any further questions about the study, please contact me on the details below.

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Trainee Clinical Psychologist

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If you wish to make a complaint about the research please contact:

Patient Experience Team
NHS Lothian, 2nd Floor
Waverley Gate
2-4 Waterloo Place
Edinburgh, EH1 3EG

0131 536 3370
feedback@nhslothian.scot.nhs.uk

If you would like to discuss this study with someone independent of the study team, please contact Dr Caroline Cochrane on:

0131 537 9128
caroline.cochrane@nhslothian.scot.nhs.uk.

Appendix 7: Consent Form

Participant Consent Form

Pain Management Research Project

Title of Research

How do self-compassion and psychological flexibility mediate change in a Compassion-Focused Therapy group for chronic pain?

Research Summary

This research aims to study how Compassion-Focused Therapy in a Pain Management Programme might work for people with chronic pain by looking into the psychological processes through which change occurs.

	Please initial
I have read and understood the Participant Information Sheet (v2 25/01/18) for the above study and have had the opportunity to consider the information and ask questions.	
I understand that my participation is voluntary and I am free to withdraw at any time, without giving a reason, without my medical care being affected.	
I understand that the treatment I receive will be unaffected by participating in the above study.	
I understand that my anonymised data will form part of a doctoral thesis, and may also be included in journal articles or academic conferences.	

I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsors (NHS Lothian and the University of Edinburgh) or from the/other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records.	
I agree to take part in the above study.	

_____

Participant's name (Printed)

_____ _____

Participant's signature Date

_____

Person taking consent (Printed)

_____ _____

Signature of person taking consent Date

Original (x1) to be retained in site file. Copy (x1) to be included in patient notes. Copy (x1) to be retained by the participant.

LOTHIAN CHRONIC PAIN SERVICE
Pain Management Programme Questionnaire

Name: _____ Date: _____

We know that living with pain is difficult. We know it affects what you can and can't do, and we know it affects how you feel. The following questionnaires will help us to determine how best we can help you, as well as being able to provide indications of your progress at the end of the Pain Management Programme.

Remember to answer all of the questions, as best you can, on both sides of the paper. Often your first answer is better than a long thought out response.

If you have any questions about these questionnaires, you can contact us on 0131-537-9128 (Astley Ainslie Hospital). *Thank you for taking the time to complete these questionnaires.*

About the intensity of your pain

Please rate your pain by circling one number that best describes how sore your pain is:

At its WORST in the last 24 hours

0	1	2	3	4	5	6	7	8	9	10
No Pain										Pain as bad as you can imagine

At its LEAST in the last 24 hours

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

On the AVERAGE

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

RIGHT NOW

0	1	2	3	4	5	6	7	8	9	10
No pain										Pain as bad as you can imagine

About the interference with life

Please circle one number that describes how, during the past 24 hours, pain has interfered with your:

General activity

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Mood

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Walking ability

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Normal work (includes both work outside the home and housework)

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Relations with other people

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Sleep

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

Enjoyment of life

0	1	2	3	4	5	6	7	8	9	10
Does not interfere										Completely interferes

In the last 2 weeks, have you had thoughts about killing or harming yourself?

Yes ☐ **No** ☐

Hospital Anxiety and Depression Scale (HADS)

Please read each item and tick the box that comes closest to how you have been feeling in the past week. Don't take too long over your replies; your immediate reaction to each item will probably be more accurate than a long thought out response. Tick only one box in each section.

I feel tense or "wound up":
- Most of the time
- A lot of the time
- From time to time, occasionally
- Not at all

I still enjoy things I used to enjoy:
- Definitely as much
- Not quite so much
- Only a little
- Hardly at all

I get a sort of frightened feeling as if something awful is about to happen:
- Very definitely, quite badly
- Yes, but not too badly
- A little, but it doesn't worry me
- Not at all

I can laugh and see the funny side of things:
- As much as I always could
- Not quite so much now
- Definitely not so much now
- Not at all

Worrying thoughts go through my mind:
- A great deal of the time
- A lot of the time
- From time to time but not too often
- Only occasionally

I feel cheerful:
- Not at all
- Not often
- Sometimes
- Most of the time

I can sit at ease and feel relaxed:
- Definitely
- Usually
- Not often
- Not at all

I feel as if I am slowed down:
- Nearly all the time
- Very often
- Sometimes
- Not at all

I get a sort of frightened feeling like "butterflies" in the stomach:
- Not at all
- Occasionally
- Quite often
- Very often

I have lost interest in my appearance:
- Definitely
- I don't take so much care as I should
- I may not take quite as much care
- I take just as much care as ever

I feel restless as if I have to be on the move:
- Very much indeed
- Quite a lot
- Not very much
- Not at all

I look forward with enjoyment to things:
- As much as I ever did
- Rather less than I used to
- Definitely less than I used to
- Hardly at all

I get sudden feelings of panic:
- Very often indeed
- Quite often
- Not very often
- Not at all

I can enjoy a good book or radio or TV programme:
- Often
- Sometimes
- Not often
- Very seldom

A	D
/21	/21

The Short Warwick-Edinburgh Mental Well-being Scale (SWEMWBS)

Below are some statements about feelings and thoughts.

Please tick the box that best describes your experience of each over the last 2 weeks.

Statements	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future	1	2	3	4	5
I've been feeling useful	1	2	3	4	5
I've been feeling relaxed	1	2	3	4	5
I've been dealing with problems well	1	2	3	4	5
I've been thinking clearly	1	2	3	4	5
I've been feeling close to other people	1	2	3	4	5
I've been able to make up my own mind about things	1	2	3	4	5

HOW I TYPICALLY ACT TOWARDS MYSELF IN DIFFICULT TIMES

Please read each statement carefully before answering. To the left of each item, indicate how often you behave in the stated manner, using the following scale:

Almost never				Almost always
1	2	3	4	5

_____1. When I fail at something important to me I become consumed by feelings of inadequacy.

_____2. I try to be understanding and patient towards those aspects of my personality I don't like.

_____3. When something painful happens I try to take a balanced view of the situation.

_____4. When I'm feeling down, I tend to feel like most other people are probably happier than I am.

_____5. I try to see my failings as part of the human condition.

_____6. When I'm going through a very hard time, I give myself the caring and tenderness I need.

_____7. When something upsets me I try to keep my emotions in balance.

_____8. When I fail at something that's important to me, I tend to feel alone in my failure

_____9. When I'm feeling down I tend to obsess and fixate on everything that's wrong.

_____10. When I feel inadequate in some way, I try to remind myself that feelings of inadequacy are shared by most people.

_____11. I'm disapproving and judgmental about my own flaws and inadequacies.

_____12. I'm intolerant and impatient towards those aspects of my personality I don't like.

Multidimensional Psychological Flexibility Inventory (MPFI)

IN THE LAST TWO WEEKS...	Never TRUE	Rarely TRUE	Occasionally TRUE	Often TRUE	Very Often TRUE	Always TRUE
1) I was receptive to observing unpleasant thoughts and feelings without interfering with them	O	O	O	O	O	O
2) I tried to make peace with my negative thoughts and feelings rather than resisting them	O	O	O	O	O	O
3) I was attentive and aware of my emotions	O	O	O	O	O	O
4) I was in tune with my thoughts and feelings from moment to moment	O	O	O	O	O	O
5) Even when I felt hurt or upset, I tried to maintain a broader perspective	O	O	O	O	O	O
6) I carried myself through tough moments by seeing my life from a larger viewpoint	O	O	O	O	O	O
7) I was able to let negative feelings come and go without getting caught up in them	O	O	O	O	O	O
8) When I was upset, I was able to let those negative feelings pass through me without clinging to them	O	O	O	O	O	O
9) I was very in-touch with what is important to me and my life	O	O	O	O	O	O
10) I stuck to my deeper priorities in life	O	O	O	O	O	O
11) Even when I stumbled in my efforts, I didn't quit working toward what is important	O	O	O	O	O	O
12) Even when times got tough, I was still able to take steps toward what I value in life	O	O	O	O	O	O

IN THE LAST TWO WEEKS...	Never TRUE	Rarely TRUE	Occasionally TRUE	Often TRUE	Very Often TRUE	Always TRUE
13) When I had a bad memory, I tried to distract myself to make it go away	O	O	O	O	O	O
14) I tried to distract myself when I felt unpleasant emotions	O	O	O	O	O	O
15) I did most things on "automatic" with little awareness of what I was doing	O	O	O	O	O	O
16) I did most things mindlessly without paying much attention	O	O	O	O	O	O
17) I thought some of my emotions were bad or inappropriate and I shouldn't feel them	O	O	O	O	O	O
18) I criticized myself for having irrational or inappropriate emotions	O	O	O	O	O	O
19) Negative thoughts and feelings tended to stick with me for a long time.	O	O	O	O	O	O
20) Distressing thoughts tended to spin around in my mind like a broken record	O	O	O	O	O	O
21) My priorities and values often fell by the wayside in my day to day life	O	O	O	O	O	O
22) When life got hectic, I often lost touch with the things I value	O	O	O	O	O	O
23) Negative feelings often trapped me in inaction	O	O	O	O	O	O
24) Negative feelings easily stalled out my plans	O	O	O	O	O	O

1	Intro and housekeeping (10)		Introductions and group guidelines Hopes & fears in 3s Primary & Secondary suffering (50)		What is chronic pain part 1 (20)	Break (15)	What is Chronic Pain Part 2 (30)	Mindfulness intro (10)	Adjustment What has helped you cope? Passengers on the bus or similar metaphor(40)						*Questionnaires*	
2	Mindfulness intro(10)		Fearless movement inc cardio (30)		Pacing (50)	Break (15)	Tricky brain CBT model (30)				Tai chi (10)	SRB & ladder (30)			*Practice SRB* *Pacing* *Exercise / movement*	
3	SRB (10)	Home practice (15)	Practical Pacing/ movement (30)	Cardio (10)	3 circles intro and practical (30)	Break (15)	Pain & Stress & coping (40)				Tai chi (10)				*Goals* *SRB* *Pacing Exercise / movement*	
4	SRB (10)	Home prac	Goals (35)		Cardio (20)	What is compassion; Coaching (20)	Break (15)	Attention (35)		Tai Chi (15)	Attention / Mindfulness practice (15)				***Goals Attention*** ***Sleep*** *SRB* *Pacing Exercise / movement*	
5	Calm place (20)	HP (15)	Compassionate thoughts (45)		Cardio (20)	Break (15)	Sleep (30)		Tai Chi (15)	Sleep (30)					***SRB Pacing*** ***Exercise Sleep*** ***Thoughts*** ***prepare1:1***	
			Individual		Individual sessions based on 3 members of staff (two facilitators plus extra)											
7	SRB (10)	Home practice (15)	Others & your pain (45)		Tai Chi (10)	Others Videos (10)	Break (15)	Cardio and start flare-up planning (30) Friends and family (30)		Flare-up planning (15)		Discuss-functional movement (15)			***Flare-up plan*** ***Communication*** *Goals* *Attention SRB* *Pacing* *Exercise / movement*	
8	Calm place (10)	Home practice (15)	Functional movement & Tai Chi (70)			Break (15)	Compassionate imagery (other)(20)		Cardio (20)		How are we coping/endings (20)				***Imagery*** ***Functional movement*** *Thoughts Goals* *Attention SRB* *Pacing*	
9	Comp image (10)	Home practice (15)	Compassion and adjustment (30)		Cardio and moving on with exercise (30)	Break (15mins)	Compassionate imagery (20 mins) (*self*)		Tai chi (20)		Goals revisited (30mins)				***Imagery*** ***Exercise / movement*** *Thoughts Goals* *Attention SRB* *Pacing*	
10	Comp image (10)	Home practice (15)	Keeping going (50)		Cardio (20)	Break and questionnaires (30)	Compassionate letter writing (30)				Tai chi (10)	Vignette (15)			*Prepare 1:1*	
11			Individual		Individual reviews 3 members of staff											